
RESPIRATORY PROTECTIVE DEVICES (RPD)
PRODUCT CATEGORY CLASSIFICATION: MULTIPLE UN CPC

PCR 2024:05
VERSION 1.0.0

VALID UNTIL 2028-09-12

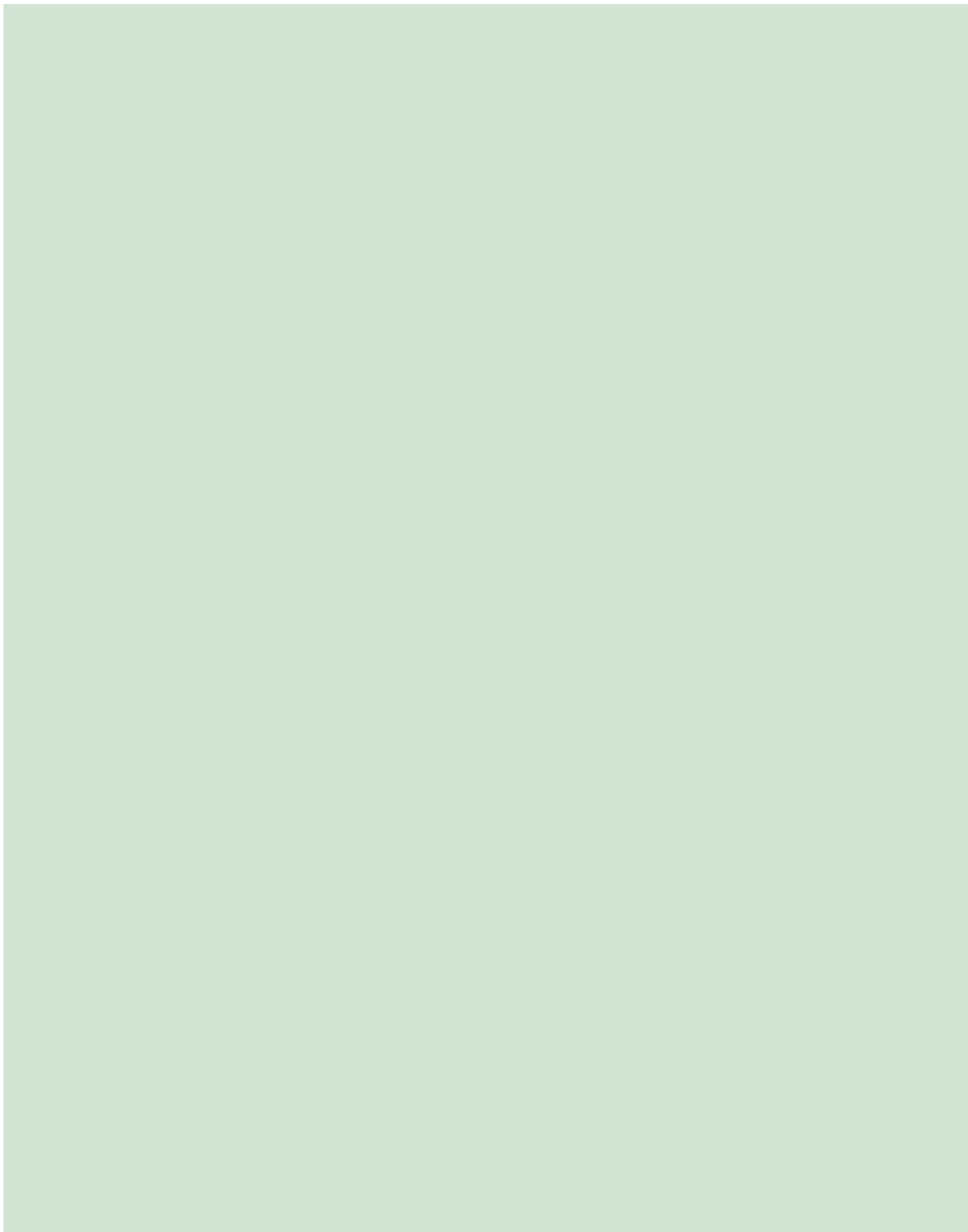


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1 INTRODUCTION

This document constitutes Product Category Rules (PCR) developed in the framework of the International EPD® System: a programme for type III environmental declarations¹ according to ISO 14025:2006, ISO 14040:2006, ISO 14044:2006, and product-specific standards such as EN 15804 and ISO 21930 for construction products. Environmental Product Declarations (EPD) are voluntary documents for a company or organisation to present transparent, consistent and verifiable information about the environmental performance of their products (goods or services).

The rules for the overall administration and operation of the programme are the General Programme Instructions (GPI), publicly available at www.environdec.com. A PCR complements the GPI and the normative standards by providing specific rules, requirements and guidelines for developing an EPD for one or more specific product categories (see Figure 1). A PCR should enable different practitioners using the PCR to generate consistent results when assessing products of the same product category.

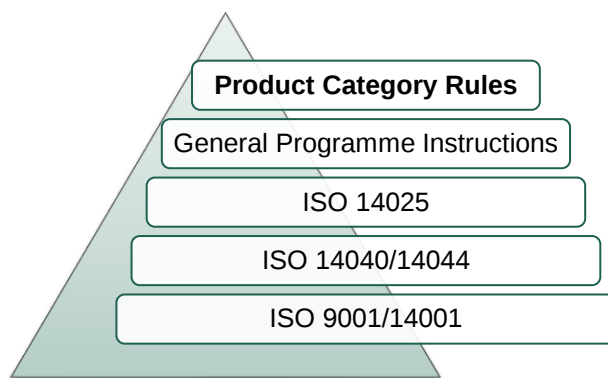


Figure 1 The hierarchy between PCRs, standards and other documents.

Within the present PCR, the following terminology is adopted:

- The term “shall” is used to indicate what is obligatory, i.e. a requirement.
- The term “should” is used to indicate a recommendation, rather than a requirement. Any deviation from a “should” requirement shall be justified in the PCR development process.
- The terms “may” or “can” is used to indicate an option that is permissible.

For definitions of further terms used in the document, see the normative standards.

A PCR is valid for a pre-determined period of time to ensure that it is updated at regular intervals. The latest version of the PCR is available at www.environdec.com. Stakeholder feedback on PCRs is very much encouraged. Any comments on this PCR may be sent directly to the PCR Moderator and/or the Secretariat during its development or during its period of validity.

Any references to this document shall include the PCR registration number, name and version.

The programme operator maintains the copyright of the document to ensure that it is possible to publish, update, and make it available to all organisations to develop and register EPDs. Stakeholders participating in PCR development should be acknowledged in the final document and on the website.

¹ Type III environmental declarations in the International EPD® System are referred to as EPDs, Environmental Product Declarations.

Name:	Respiratory protective devices (RPD)
Registration number and version:	2024:05
Programme:	The International EPD® System
Programme operator:	EPD International AB, Box 210 60, SE-100 31 Stockholm, Sweden. Website: www.environdec.com E-mail: info@environdec.com
PCR Moderators:	Detlef Tibax, 3M, dtibax@mmm.com Brendan Edgerton, 3M, bedgerton@mmm.com
PCR Committee:	ESF (European Safety Federation), 3M, Dr. Paolo Simon Ostan
Date of publication and last revision:	2024-09-12 (Version 1.0.0)
Valid until:	2028-09-12
Schedule for renewal:	A PCR is valid for a pre-determined time period to ensure that it is updated at regular intervals. When the PCR is about to expire, the PCR Moderator shall initiate a discussion with the Secretariat how to proceed with updating the PCR and renewing its validity. A PCR may also be updated without prolonging its period of validity, providing that significant and well-justified proposals for changes or amendments are presented. See www.environdec.com for the latest version of the PCR. When there has been an update of the PCR, the new version should be used to develop EPDs. The old version may however be used for 90 days after the publication date of the new version, as long as the old version has not expired.
Standards and documents conformance:	General Programme Instructions of the International EPD® System, version 4.0, based on ISO 14025 and ISO 14040/14044.
PCR language(s):	At the time of publication, this PCR was available in English. If the PCR is available in several languages, these are available at www.environdec.com . In case of translated versions, the English version takes precedence in case of any discrepancies.

2.2.1 INTRODUCTION TO RESPIRATORY PROTECTIVE DEVICES (RPD)

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public spaces, etc.) to help prevent the inhalation of harmful substances such as dust, fumes, vapours, biological agents, toxic gases and exposure to atmospheres dangerous for health. RPDs can be classified into two main categories:

- Air-purifying RPDs: filtering devices dependent on ambient air where the level of oxygen and concentrations of contaminants are in the limit for the specific RPD, and
- Atmosphere-supplying RPDs: independent from ambient air and/or designed for emergency use.

It is important to choose the appropriate RPD based on the type and concentration of hazard as well as the specific requirements of the application and wearer. Additionally, proper use and maintenance of the RPD is crucial for ensuring its effectiveness and wearer safety. This includes proper face fit testing, use and maintenance training, and regular inspection and replacement of the mask, filters, or cartridges.

2.2.1.1. Legislative frameworks

RPDs are designed to protect wearers from inhaling hazardous substances. There are several legislative frameworks that govern the design and use of these devices. It's important to note that the specific legislative requirements for RPDs can vary depending on the jurisdiction, region, and industry (examples include – but are not limited to – FFP1/2/3, N95, R99, P100, CA-N95-100P, CA-R100, etc.). Employers should consult the relevant regulations and standards to ensure they comply with the requirements for their particular workplace.

2.2.1.2. Terms and definitions

Below are the terms and definitions relevant to this PCR:

- Mask/Facepiece/Respiratory Interface (RI): throughout this document, these terms are used interchangeably when describing RPDs, and are similar to one another depending on the geographical region, the regulatory framework, etc. The terms 'mask' or 'facepiece' are predominantly used to align with the wording in the referenced UN CPC Classification system and its customs codes descriptions, as well as any other referenced PCRs. It can be defined as the part of a respiratory device that forms the protective barrier between the wearer's respiratory tract and the ambient atmosphere².
- Respiratory protective device (RPD): A general term used to describe all types of respiratory protective equipment, including respirators and breathing apparatuses that follow local laws and/or regulations and/or specific technical standards. RPDs are designed to protect the wearer from external hazards by passing air through a gas filter(s), particle filter(s) or combined filter(s) before being inhaled and are not designed to protect the environment or persons other than the wearer (a combination of both functions is, in some cases, possible). RPDs can be either assisted or unassisted (i.e., actively or non-actively supplying breathable air/gas).
- Single-use RPD/Filtering Facepiece² (hereafter named 'single-use' for simplicity): A type of RPD that is designed for single or limited-use only, and not designed for repeated applications after initial use. It is made entirely or substantially constructed of a filtering material that captures contaminants in the air, preventing them from entering the wearer's respiratory system. Once the RPD becomes clogged with particles- or gas/vapour filter is full, the whole device is disposed of and replaced with a new one.
- Reusable RPD: A type of RPD that is designed to be worn multiple times (i.e., to be used for more than a single shift), if it is properly cleaned and maintained². It typically has replaceable filters or cartridges that must be changed when they become clogged (filters) or fully utilized (cartridges) or damaged. Some of these RPDs can also optionally be used as part of a PAPR, SCBA or SA system. Reusable RPDs can be made of different materials, such as silicone or rubber. These devices are typically "Half" or "Full" face as below:
 - Half-Face Respiratory Interface (RI): A type of RPD that covers the nose and mouth and is equipped with filter(s) or cartridges(s).
 - Full-Face Respiratory Interface (RI): A type of RPD that covers the entire face and is equipped with filter(s) or cartridges(s). It is often used when eye protection is required.
- Particle Filtering facepiece (FFP): A type of RPD that filters particles dusts, fumes, and aerosols. FFPs are classified based on their level of filtration efficiency and geographical region (e.g., FFP1, FFP2, or FFP3 in Europe, N95, N99, R95, P100 in the US, CA-N95 in Canada, etc.).

² The definition in ISO16792 / ISO 16975 were used to describe this term.

- Powered Air Purifying Respirators (PAPR): A type of powered filtering respiratory device/filtering RPD in which air is moved through the filter by means of a blower to supply the wearer with breathable air.³
- Self-Contained Breathing Apparatus (SCBA): A type of RPD consists of a Full-Face mask or half mask fitted with a demand valve and supplied with breathable gas from a one or more pressure vessel(s) (e.g. a cylinder).
- Supplier Air Respirators (SAR): A type of RPD that uses airline to provide breathable air. They have an airline connected to a qualified air supply either a soft hood, a helmet type device, or a Half-Face RPD or Full-Face RPD.
- European Standards (EN): A series of standards developed by the European Committee for Standardization (CEN) that define requirements and test methods for various types of RPDs.
- Exhalation Valve: A one-way valve that allows for easy exhalation and may help reduce moisture build-up inside the RPD.
- Filter: Device intended to remove specific contaminants from the ambient air passing through it³. The filter element can protect against particulate (particle filter), gases and vapours (gas filters) and particulates, gases and vapours (combined filters), as specified by the manufacturer.
- Source of breathable air: The source of air that is of a quality that makes it suitable for safe respiration. The most used air supply sources are cylinders containing compressed breathing air.
- Oxygen deficiency: A condition where the concentration of oxygen in the air is below the normal levels required to sustain human life and maintain bodily functions.
- Packaging: This may include consumer packaging, product wrapping material, user information manuals, secondary or distribution packaging, such as shipper cases and pallets.
- Hood: Hoods refer to the headworn part of the RPD system. These can be made from a fabric, or a plastic or other material.

2.2.2 PRODUCTS INCLUDED IN THIS PCR

This document provides Product Category Rules for estimating the environmental performance of RPD systems and the declaring of this performance in an EPD. The product category corresponds to subsets of multiple UN Central product classification (CPC) codes (see Table 1 for further information).

The type of RPD used will depend on the specific hazard and the level of protection required. There are several types of RPD, including:

- Single-use RPDs: These are designed to be discarded after use, rather than cleaned and reused, and are commonly used in healthcare and other occupational and public settings. Many single-use RPDs are particle filtering facepiece respirators. Examples include (but are not limited to) N95, CA-N95-100Pa, CA-P100, or FFP2 respirators.
- Reusable RPDs: These are designed for multiple uses and thus, typically made of more durable materials. Reusable RPDs must be explicitly designed for multiple use cycles. RPD types included in this category are:
 - Passive reusable RPDs: These include unpowered half- and full-face RPDs.
 - Powered air-purifying RPDs (PAPRs): These use a battery-operated blower to filter and deliver the air to the user through a mask or hood.
 - Self-contained breathing apparatus (SCBA): These are used in hazardous environments where oxygen deficiency or toxic gases occur. SCBAs typically consist of a compressed air tank, regulator, and a mask.
 - Escape RPDs: These are designed to be used in emergency situations where the wearer must quickly escape from a hazardous environment.
 - Supplied air RPDs (SARs): These use a source of clean air that is separate from the environment and delivered to the wearer through a mask or hood.

However, the following articles are outside of the scope of this PCR:

- Disposal surgical masks that **only** have the purpose to protect the patient and environment **and not** the wearer. These are products that only comply to EN14683 and are covered by PCR 2017:01 from the International EPD® System.
- Replacement and maintenance of RPD components.

³ As described in ISO 16792 / ISO 16975.

- Respiratory protection specifically designed for public defence and military.
- Respiratory and rescue systems for exclusive use on vessels, aircrafts and spacecrafts.
- Self-contained underwater breathing apparatus
- Comfort and paper masks
- Resuscitators, and
- Replaceable elements defined as additional parts that don't support the respiratory protection of the wearer of the RPD

A more detailed list of RPDs is given in Annex A.

Due to the different types of RPDs and the different conditions where they are used, the RPD sector is highly complex and diverse. Production and use of RPDs involves all stakeholders: designers, manufacturers, professional users and consumers. Consequently, this document is developed based on a multi-CPC code and multi-material approach. In addition, this PCR is developed modularly regarding the life cycle stages and the system boundaries.

2.2.2.1. UN CPC Classification

This PCR represents a generic product category with a wide range of RPD, making it difficult to classify according to UN CPC classification. The CPC codes on RPD have the following drawbacks:

- not all codes are available (e.g., incomplete classification of materials),
- descriptions are often non-existent or incomplete,
- and innovative solutions are not covered.

To overcome these structural problems in the CPC classification, the main function of the RPD should be checked in any relevant product technical documentation and matched with a given CPC code description, allowing the EPD Owner to easily identify the most appropriate CPC code for each product.

The description of the CPC codes may not be fully applicable to the product of the EPD as they may refer to items excluded from the scope of this PCR. Despite this, the CPC code should still be used to define the product concerned. Where it is not possible to assign a CPC code with an adequate description, a generic CPC code (e.g. 362 or 363) shall be assigned, or alternatively, a product classification following other international standards shall be assigned to the product if a generic CPC code cannot be identified.

Table 1 below shows some examples of CPC codes identified. As the table is a non-exhaustive list, other CPC codes may also be relevant. See <https://unstats.un.org/unsd/classifications/Family/Detail/1074> for additional information. Because CPC codes are infrequently used and, in some cases, not sufficiently specifying products, a third column in Table 1 is added to help further determine the CPC classification by using the HS 2007 code from the Harmonized Commodity Description and Coding System (Harmonized System), in combination with the TARIC/CN codes which are more commonly used.

See <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1998> for additional information.

RESPIRATORY PROTECTIVE DEVICES (RPD)
PRODUCT CATEGORY CLASSIFICATION: MULTIPLE UN CPC

Table 1 Non-exhaustive list of UN CPC codes and descriptions included in the scope of this PCR⁴, if the application of the product is used as RPD

UN CPC	CPC DESCRIPTION	POTENTIAL RPDs INCLUDED	CUSTOMS CODES - EU COMMISSION IMPLEMENTING REGULATION (EU) 2022/1998
27190	Other made-up textile articles (including floor [1] cloths, dish-cloths, dusters and similar cleaning cloths, life-jackets and life-belts)	Filtering facepiece RPDs	6307.90 - Textile face-masks, without a replaceable filter or mechanical parts, including surgical masks and disposable face-masks made of non-woven textiles. This includes the masks known as N95 Particulate Respirators. Note: the heading also includes N95 respirators with simple exhalation valves as these remain respirator masks and are not gas masks 6307.9093 - Filtering facepieces (FFP) according to EN149, and other masks conforming to a similar standard for masks as respiratory protective devices to protect against particles 6307.9095 - Protective face masks (excl. filtering facepieces FFP according to EN149, and other masks conforming to a similar standard for masks as respiratory protective devices to protect against particles)
48160	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; other breathing appliances and gas masks (excluding protective masks having neither mechanical parts nor replaceable filters)	Half facepiece RPDs Full facepiece RPDs Escape hoods PAPRs SARs SCBA	9020.00 - Breathing appliances and gas masks. Gas masks with mechanical parts or replaceable filters for protection against biological agents. Also includes such masks incorporating eye protection or facial shields. 9020.0010 - Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters: gas masks 9020.0090 - Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters: other, including parts and replaceable elements

⁴ As defined by the CPC Classification System (see weblink on the previous page).

2.2.3 GEOGRAPHICAL SCOPE

This PCR may be used globally.

2.2.4 EPD VALIDITY

An EPD based on this PCR shall be valid for a 5-year period starting from the date of the verification report ("approval date"), or until the EPD has been de-registered from the International EPD® System.

An EPD shall be updated and re-verified during its validity if changes in technology or other circumstances have led to:

- an increase of 10% or more of any of the declared indicators of environmental impact,
- errors in the declared information, or
- significant changes to the declared product information, content declaration, or additional environmental, social or economic information.

If such changes have occurred, but the EPD is not updated, the EPD owner shall contact the Secretariat to de-register the EPD.

3 PCR REVIEW AND BACKGROUND INFORMATION

This PCR was developed in accordance with the PCR development process described in the GPI of the International EPD® System, including open consultation and review.

3.1 OPEN CONSULTATION

3.1.1 VERSION 1.0.0

This PCR was available for open consultation from 2023-07-17 until 2023-09-17, during which any stakeholder was able to provide comments by contacting the PCR Moderator and/or the Secretariat.

Stakeholders were invited via e-mail or other means to take part in the open consultation and were encouraged to forward the invitation to other relevant stakeholders. The following stakeholders provided comments during the open consultation and agreed to be listed as contributors in the PCR and at www.environdec.com.

- *Dräger Safety AG & Co. KGaA*
- *European Safety Federation*
- *Intersafe - a Lyreco Company*
- *Life Cycle Strategies Pty Ltd*

3.2 PCR REVIEW

3.2.1 VERSION 1.0

PCR review panel:	The Technical Committee of the International EPD® System. A full list of members is available at www.environdec.com . The review panel may be contacted via info@environdec.com . Members of the Technical Committee were requested to state any potential conflict of interest with the PCR Committee, and if there were conflicts of interest they were excused from the review.
Chair of the PCR review:	Nasser Ayoub
Review dates:	2024-05-13 until 2024-06-25

3.3 EXISTING PCRS FOR THE PRODUCT CATEGORY

As part of the development of this PCR, existing PCRs and other internationally standardized methods that could potentially act as PCRs were considered to avoid unnecessary overlaps in scope and to ensure harmonisation with established methods of relevance for the product category. The existence of such documents was checked among the following EPD programmes and international standardisation bodies:

- The International EPD® System. www.environdec.com.
- The Norwegian EPD Foundation
- EPDIItaly
- IBU
- PEP ecopassport®

Table 2 lists the identified PCRs and other standardized methods.

Table 2 Existing PCRs and other internationally standardized.

NAME OF PCR/STANDARD	PROGRAMME/ STANDARDISATION BODY	REGISTRATION NUMBER, VERSION NUMBER/DATE OF PUBLICATION	SCOPE
Disposable surgical drapes, gowns, air suits and face masks used for patients, clinical staff and equipment.	The International EPD® System	2017:01 v2.0 – expected publication date 2023-07-01	Disposable surgical drapes, gowns, air suits and face masks used for patients, clinical staff and equipment. UN CPC 35290
Electrical motors and generators and parts thereof (for industrial applications)	The International EPD® System	2022:06 v1.0 – 2022-10-11	Electrical AC and DC motors and generators for industry applications and some of their parts: rotors and stators. The power range of products included in the scope are from 0.1kW and above, voltage range between 50V and 110 000V. UN CPC 46112 & 46131

PCR 2017:01 includes disposal surgical masks, which are excluded from the scope of this PCR per Section 2.2.2 Product Category Definition and Description. Consequently, there is no overlap between the two PCRs. PCR 2022:06 covers industrial applications like water and waste-water pumps, cooling fans, compressors, mixers, gas and steam turbine, gas-and diesel engine, wind turbines, conveyors in several industrial segments like pulp and paper, mining, power, oil and gas, marine, etc, so no overlap with these electrical components included in this PCR.

No other existing PCRs or internationally standardized methods with overlapping scope were identified.

3.4 REASONING FOR DEVELOPMENT OF PCR

This PCR was developed to enable publication of EPDs for this product category based on ISO 14025, ISO 14040/14044. The PCR enables different practitioners to generate consistent results when assessing the environmental impact of products of the same product category, and thereby it supports comparability of products within a product category.

3.5 UNDERLYING STUDIES USED FOR PCR DEVELOPMENT

The methodological choices made during the development of this PCR (e.g. declared/functional unit, system boundary, allocation methods, impact categories, data quality rules, etc.) were primarily based on the following underlying studies:

- Depelchin, Jonas. *Life Cycle Assessment (LCA) – 3M™ Aura™ 9300+ Series Respirators*, rev. 2 – December 2012.
- Softa, Katerina. *Life Cycle Assessment (LCA) – 3M™ 8825/35 and 8825/35+ Disposable Respirators*, rev. 1 – April 2016.
- Tibax, Detlef. *Life Cycle Assessment (LCA) / Pre-verified EPD study - 3M™ Aura™ Respirators 9300+ and 9300+Gen3 Series*, rev. 1 – September 2023.

4 GOAL AND SCOPE, LIFE CYCLE INVENTORY AND LIFE CYCLE IMPACT ASSESSMENT

The goal of this section is to provide specific rules, requirements and guidelines for developing an EPD for the product category as defined in Section 2.2.

4.1 DECLARED UNIT

The declared unit is defined as one (1) RPD system including the main system, components, packaging and all replaceable elements required to fulfil the technical performance and protection intended by the product design for an initial use.

To clearly differentiate between RPD elements that determine the scope of the EPD (i.e. the main RPD system and RPD replaceable elements), the following rules and definitions shall be followed:

- Main RPD system: the part of the RPD with typically the longest technical lifespan including the components⁵ that are considered to have the same lifespan. The main system is the core, or essential, part of the RPD which is critical for a proper functionality of the RPD but is by default not expected to be replaced. While this is typically the mask or body of the RPD, it may be another part (e.g., the fan system for PAPRs with hoods or replaceable masks). Components of the main RPD system may be replaced – due to breaking or failure – despite the designed intention to have the same technical lifespan as the main RPD system and are therefore considered to be part of the main RPD system as well. Examples of components are tubes, valves, headbands. The replacement and maintenance of components is excluded from the scope of this PCR.
- Replaceable elements: consumable parts intended to be replaced during the use stage of the main RPD system. Based on the type of respirator, these parts may include filters/cartridges, hoods or replaceable masks⁶, single-use batteries, cylinders and/or other replaceable elements required to be replaced during the use stage of the main RPD system. All relevant replaceable elements required for initial use⁷ shall be considered in the LCA. For each of these replaceable elements a different module is created in Section 4.3.

The declared unit shall be stated in the EPD. The environmental impact shall be given per declared unit. A description of the function of the product shall be included in the EPD, if relevant, and will be defined via the product information given in Section 5.4.3.

A general functional unit cannot be defined since the possible downstream applications (and thus functions and qualitative aspects) and the conditions of use of RPDs and their components are widely variable (e.g., an air filter cartridge can have a significantly different lifespan depending on specific chemical exposure, temperature, humidity, etc.). The complexity of this subject is further confirmed by all standards for the selection and use of RPDs⁸. The scope of use depends on risk evaluation and refers to proper hazards defined by users or safety manager. To ensure broad applicability, this PCR adopts a modular approach, as described in Section 4.3. This approach allows EPD users to have useful information to make a fair comparison between different EPDs (see Section 4.2 and Annex C for further information). However, when it is possible to define the function of a certain RPD, an optional functional unit may be used and declared as additional environmental information. See Section 4.1.1 below.

For any product, the assessment of the technical performance (i.e., the measurement and/or calculation of performance characteristics of the product) is based on operation in the product's optimal application setting under the most extreme circumstances. This optimal application setting is the foundation for the product and its use description and shall be stated in the EPD.

⁵ Accessories are not included in the scope of the PCR. Accessories are defined as additional parts that can be added on the RPD, but don't have a respiratory protection function. An example is a mining lamp that can be plugged on the RPD.

⁶ A mask is seen as a replaceable element when it is expected to be replaced, like a hood, during the lifespan of the main RPD system.

⁷ Initial use refers to readying one (1) complete product system for its first operational use, which may involve e.g., plugging the filters on the main RPD system, connecting the cylinders, or charging the battery set completely. Only one set of the replaceable elements (if these elements are part of the product system) shall be considered.

⁸ One such example is Section A.2.4.3 in EN 529 'Respiratory protective devices - Recommendations for selection, use, care, and maintenance' Guidance Document, which states that 'it is difficult to give a "general rule of thumb" advice for the safe duration of use (service life) for a gas filter'.

4.1.1 FUNCTIONAL UNIT

An optional functional unit of 1 cycle of use may be reported for reusable RPDs by rescaling the given components based on their individual specified technical lifespan. The environmental performance related to this functional unit shall be reported as additional environmental indicators under the additional information and the EPD shall contain an explanation of the difference between the different sets of indicators, as they may appear to the reader to display duplicate information.

4.2 TECHNICAL LIFESPAN / REFERENCE SERVICE LIFE (RSL)

For EPDs based on this PCR, as mentioned in Section 4.1, a meaningful lifespan or RSL for main RPD systems and/or replaceable elements cannot be pre-defined. This is because the technical lifespan for any RPD type can vary based on several factors, including the manufacturer's recommendations, the level of exposure to contaminants, environmental conditions, and the type and condition of the RPD.

When an EPD user wants to compare EPDs of different RPDs (e.g., EPDs of single-use and EPDs of reusable RPDs), the single-use and reusable products shall perform the same function and the EPD user should use the calculation rules in Annex C to ensure a fair comparison. Furthermore, EPD users will need to define an 'estimated' technical lifespan for the products in the EPDs based on their intended application and specific use conditions (referring to professional use^{Error! Bookmark not defined.} only, and still ensuring continued effectiveness of the RPD system) to perform the comparison. If such a lifespan can be estimated, it should follow the manufacturer's instructions for use, inspection, maintenance, and, where applicable, routine servicing. It shall not consider the shelf life of the RPD.

Comparisons and interpretations of the results obtained after applying the calculation rules in Annex C shall be done with caution and are not to be considered univocally valid. Further guidance is given in Annex C.

The EPD shall include the following statement in the Environmental performance section: *Comparisons of EPDs of different respiratory protective devices shall only be done if the products perform the same function. If the results of different EPDs are recalculated for a certain use scenario, the rules in Annex C of the PCR shall be used. Such use scenarios shall include an estimated technical lifespan and should follow the manufacturer's instructions for use, inspection, maintenance, and, where applicable, routine servicing.*

4.3 SYSTEM BOUNDARY

The scope of this PCR and derived EPDs is cradle-to-grave.

4.3.1 LIFE-CYCLE STAGES

For transparency and comparability, the life cycle of an RPD is divided into three life cycle stages:

- Upstream processes (from cradle-to-gate)
- Core processes (from gate-to-gate)
- Downstream processes (from gate-to-grave)

In an EPD, the environmental performance associated with each of the three life-cycle stages above shall be reported separately and in aggregated form. The processes included in the scope of the PCR and belonging to each life cycle stage are described in Sections 4.3.1.1–4.3.1.3.

Further, EPDs shall present the environmental performance results divided into the life-cycle modules A1-C5 (Bx and Cx as optional), or module groups (e.g. A1-A3, A4-A5). The possible modules to be considered are given in Table 3 per RPD type. In the EPD, a similar table shall be reported to declare the modules in scope (see Section 5.4.3).

An important element to define which processes to include in the different modules is by identifying the main RPD system and differentiate it from the replaceable elements that are expected to be replaced during the life cycle of the main RPD system. As described in Section 4.1, replaceable elements such as filters, hoods or replaceable masks⁹, single-use batteries, cylinders and other replaceable

⁹ By excluding hoods and some masks from the main RPD system, the part of the RPD that covers mouth and nose is not always the main RPD system. In those cases, the main RPD system can be the motor, fan and/or reusable battery and will be reported under A1-A3 and the hood or mask will be reported under B3.

elements are reported in the use modules (B2-B5, Bx¹⁰) whilst the main RPD system with its non-replaceable components are reported under the product stage (A1-A3)¹¹. In the use modules (B2-B5, Bx) each replaceable element, required for initial use of the RPD system, shall be considered only once (1 unit/piece) and not for the total number of replacements during the estimated technical lifespan.

This PCR includes these replaceable elements in the use stage under different modules because:

- Replaceable elements are expected to be replaced during the lifetime of the main RPD system, and as each replaceable element can have a different technical lifespan, the number of replacements may vary.
- The main RPD system and replaceable elements can be sold separately and there is no unique combination between the main RPD system and the replaceable elements¹².
- The use stage is considered to be the stage where the main RPD system is prepared for initial use (e.g. plugging the filters on the main RPD system, connecting the cylinders or charging the battery completely¹³).
- Knowing the impact of one replaceable element and one main RPD system gives the flexibility to the RPD wearer/EPD user to determine the complete life cycle impacts of the RPD based on specific use conditions¹⁴ and determining their estimated technical lifespans. The RPD user can compare the results of different EPDs by using the guidance provided in Annex C.

By describing the technical performance of each replaceable element, the differences in performance are clarified and substantiated in the EPD, and RPD wearers/EPD users will be able to estimate technical lifespans, should they wish to compare EPDs. See Annex C for further information. Reference to test reports, manufacturers published user information and applied standards shall be made to substantiate the data and information used to describe the function and use conditions of the RPD.

It is apparent from this section that RPDs and their replaceable elements can be reported in a large variety of user scenarios. Various replaceable elements like filters and cartridges with differing characteristics and lifespans can be used on the same type of RPD systems, but the EPD owner shall clearly define in the EPD the scenario adopted and the characteristics of the replaceable elements that have been chosen in accordance with that specific scenario.

¹⁰ Bx are optional modules that can be included when a RPD has one or more other replaceable elements next to filters (B2), hoods or replaceable masks (B3), disposable batteries (B4) or cylinders (B5). E.g. if there is one additional replaceable element the module shall be called B6. In the case of two different additional replaceable elements two modules are created, respectively B6 and B7 shall be created. If there are no additional replaceable elements, the module shall not be reported. Components of the main RPD system are not part of the other replaceable elements but are reported under A1-A3.

¹¹ In cases where the lifetime of one of the 4 replaceable elements is longer than the main RPD system, they will still be reported under the use modules. Example of this can be cylinders that have a longer lifespan than the mask, but still the mask will be reported under A1-A3 and the cylinders under B5.

¹² E.g. the main RPD system allows the use of different filters to be used in different circumstances. The complete RPD shall be included in the EPD representing a unique combination of the main RPD system and relevant replaceable elements.

¹³ The only exception occurs when an external air supply is used (e.g. compressor), requiring the recognition of its associated energy consumption for a continuous shift of 8 hours.

¹⁴ Done by multiplying the relevant modules with a certain amount of uses. For example, if during the life cycle of the main RPD system 50 filter units are used, replaced and disposed, the relevant modules can be multiplied with 50.

RESPIRATORY PROTECTIVE DEVICES (RPD)
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Table 3 The life cycle of different RPDs divided into three life cycle stages according to the General Programme Instructions, four life cycle module groups and 15 possible life cycle modules

LIFE CYCLE PHASE	LIFE CYCLE MODULE GROUP	LIFE CYCLE MODULE	POSSIBLE MODULES INCLUDED IN THE SYSTEM BOUNDARIES (NOT EXHAUSTIVE) ¹⁵					
			Single-use RPDs	Passive reusable RPDs	PAPRs	SCBAs	Escape RPDs	SARs
Upstream	A1-A3)	A1) Raw material supply	X	X	X	X	X	X
Core	Product ¹⁶ stage	A2) Transportation	X	X	X	X	X	X
		A3) Manufacturing	X	X	X	X	X	X
Downstream	A4-A5)	A4) Transportation	X	X	X	X	X	X
	Distribution stage	A5) Waste treatment of distribution packaging	X	X	X	X	X	X
	B1-B5, Bx) Use stage	B1) Waste treatment of main RPD system packaging	X	X	X	X	X	X
		B2) Filters		X	X		X ¹⁷	
		B3) Hoods or replaceable masks			X	X	X ¹⁷	X
		B4) Battery power supply			X	X	X ¹⁷	
		B5) Air supply				X	X ¹⁷	X
		Bx ¹⁸) Other replaceable elements		(X)	(X)	(X)	(X)	(X)
	C1-C5, Cx) End of life stage	C1) Main RPD system disposal	X	X	X	X	X	X
		C2) Filter disposal		X	X		X ¹⁷	
		C3) Hood or replaceable mask disposal			X	X	X ¹⁷	X
		C4) Disposable battery disposal			X	X	X ¹⁷	
		C5) Cylinder disposal				X	X ¹⁷	X
		Cx ¹⁸) Other replaceable elements disposal		(X)	(X)	(X)	(X)	(X)

¹⁵ For any reusable RPDs, 'X' is typically applicable, but not in all cases (e.g., not all reusable RPDs have replaceable elements, thus the inclusion of the relevant module does sometimes not apply)

¹⁶ Main RPD system, its packaging and components

¹⁷ Escape RPDs vary a lot in design and therefore can contain different specific replaceable elements.

¹⁸ Numbering shall start with 6 and be consecutive based on the amount of additional other replaceable elements.

RESPIRATORY PROTECTIVE DEVICES

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4.3.1.1. Upstream processes

Single-use RPDs: the upstream processes of all components and parts are included.

Reusable RPDs: Upstream processes are only relevant for the main RPD system as described in Section 4.1. Therefore, the raw materials of filters, hoods or replaceable masks, single-use batteries, cylinders and other replaceable elements are excluded from the upstream processes.

The following unit processes are part of the product system and shall be classified as upstream processes:

A1) Raw material supply

- extraction and processing of raw materials used for the main RPD system,
- recycling processes of secondary materials from other product life cycles,
- production of auxiliary products (e.g. cleaning chemicals) used in upstream and core processes of the main RPD system,
- relevant services, such as transport of raw materials and components along the upstream supply chain to a distribution point (e.g. a stockroom or warehouse),
- production and distribution¹⁹ of raw materials and product packaging²⁰ of the main RPD system,
- generation of electricity and production of fuels, steam and other energy carriers used in upstream processes, and
- end-of-life treatment of upstream waste.

Upstream processes not listed may also be included. All elementary flows at resource extraction shall be included, except for the flows that fall under the general cut-off rule in Section 4.5.

The following processes shall not be included:

- For reusable RPDs the raw materials, packaging and auxiliary products used in the manufacturing of filters, hoods or replaceable masks, single-use batteries, cylinders, and other replaceable elements, and
- generation of electricity and production of fuels, steam and other energy carriers used in core processes (see Section 4.3.1.2).

4.3.1.2. Core processes

For reusable RPDs, core processes are only relevant for the main RPD system, as described in Section 4.1. Therefore, the raw material transportation and production of filters, hoods or replaceable masks, single-use batteries, cylinders and other replaceable elements are excluded from the core processes. For single-use RPDs the core processes of all components and parts are included.

The following unit processes are part of the product system and shall be classified as core processes:

A2) Transportation

- external transportation of materials and components to the manufacturing site of the main RPD system, and
- generation of fuels used in the transportation.

A3) Manufacturing

- manufacturing of the main RPD system,
- internal transportation of intermediates to the manufacturing site of the main RPD system,
- end-of-life treatment of waste generated during the manufacturing of the main RPD system, even if carried out by third parties (including transportation) and
- generation of electricity and production of fuels, steam and other energy carriers used in core processes.

Core processes not listed may also be included. At least 99% of the total weight of both the main RPD system and packaging must be included. The following processes shall not be included:

¹⁹ See Section 5.4.4.2 for definition

²⁰ Product packaging is defined to be consumer packaging (see Section 5.4.4.2 for definition) as well as any leaflet and/or user instruction that are included in the in the consumer packaging.

- For reusable products the manufacturing of filters, hoods or replaceable masks, single-use batteries, cylinders, and other replaceable elements,
- manufacturing and end-of-life of infrastructure and capital goods (with a few exceptions, see Section 4.3.2),
- business travel of personnel,
- travel to and from work by personnel, and
- research and development activities.

4.3.1.3. Downstream processes

The following unit processes are part of the product system and shall be classified as downstream processes:

Modules A4-A5 described below are only relevant for the main RPD system, its packaging and components as described in modules A1-A3.

A4) Transportation

- transportation of the main RPD system to retailer/distribution platform/consumer, and
- transportation to location of use.

A5) Waste treatment of distribution packaging

- end-of-life treatment of the distribution packaging of the main RPD system, including transportation to the disposal/recovery site.

Modules B1-B5, Bx described below are representing the different possible replaceable elements. Each of the replaceable elements are reported for one unit (e.g. one filter or one pair of filters, one hood, etc.).

B1) Waste treatment of main RPD system packaging

- Waste disposal of the main RPD system's product packaging (e.g. consumer packaging and leaflets/user instructions) including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the "polluter pays principle",
- Transportation of the discarded main RPD system to the disposal or recycling site.

B2) Filter(s)

- all unit processes applicable to the filter(s) and as described in modules A1-A5. These processes are, but are not limited to:
 - raw material extraction and processing used in the manufacturing of the filter unit and its packaging,
 - transport of raw materials to the filter unit production site,
 - manufacturing of the filter unit,
 - distribution of the filter unit, and
 - filter unit packaging disposal.

B3) Hoods or replaceable masks

- all unit processes applicable to the hood or replaceable mask and as described in modules A1-A5. These processes are, but are not limited to:
 - raw material extraction and processing used in the manufacturing of the hood or replaceable mask and its packaging,
 - transport of raw materials to the hood or replaceable mask production site,
 - manufacturing of the hood or replaceable mask,
 - distribution of the hood or replaceable mask, and
 - hood or replaceable mask packaging disposal.

B4) Battery power supply

- For single-use batteries: all unit processes applicable to the single-use disposal battery(ies) and as described in modules A1-A5. These processes are, but are not limited to:

- raw material extraction and processing used in the manufacturing of the single-use disposal battery(ies) and its packaging,
 - transport of raw materials to the single-use disposal battery(ies) production site,
 - manufacturing of the single-use disposal battery(ies),
 - distribution of the single-use disposal battery(ies),
 - single-use disposal battery(ies) packaging disposal, and
- For reusable batteries: energy use to charge the reusable battery from 0% to 100% power.

The following processes shall not be included:

- manufacturing of reusable batteries as they are part of the main RPD system included in modules A1-A5.

B5) Air supply

- For RPDs using air cylinders: all unit processes applicable to the cylinder(s) and as described in modules A1-A5. These processes are, but are not limited to:
 - raw material extraction and processing used in the manufacturing of the cylinder(s) and its packaging,
 - transport of raw materials to the cylinder(s) production site,
 - manufacturing of the cylinder(s),
 - filling the cylinders with oxygen/air,
 - distribution of the cylinder(s),
 - cylinder(s) packaging disposal, and
- For RPDs using and external air supply: energy use to supply air by an external compressor²¹ for 8 h.

The following processes shall not be included:

- manufacturing of the compressor as it is considered a capital good.

Bx²²) Other replaceable elements

This module is an optional module and is only in scope of the EPD when the RPD has another replaceable element that is expected to be replaced and it is not a filter (B2), hood or replaceable mask (B3), disposable battery (B4) or cylinder (B5)

- all unit processes applicable to the other replaceable element and as described in modules A1-A5. These processes are, but are not limited to:
 - raw material extraction and processing used in the manufacturing of the other replaceable element and its packaging,
 - transport of raw materials to the other replaceable element production site,
 - manufacturing of the other replaceable element,
 - distribution of the other replaceable element, and
 - other replaceable element packaging disposal

C1) Main RPD system disposal

- Waste disposal of the main RPD system and its components, including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the "polluter pays principle", and
- Transportation of the discarded main RPD system to the disposal or recycling site.

²¹ A compressor is a device used to supply compressed air to a respirator. The compressor takes in ambient air, compresses it to a higher pressure, and delivers it to the respirator wearer through a hose or airline system. The hose and airline system are part of the main RPD system and not reported under module B5. The compressor may be an electrically powered machine that compresses the ambient air or a cylinder-driven compressor powered by an internal combustion engine.

²² Number and name of the module shall be changed accordingly in the EPD.

C2) Filter(s) disposal

- Waste disposal of the filter(s) unit, including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the “polluter pays principle”, and
- Transportation of the discarded filter unit to the disposal or recycling site.

C3) Hood or replaceable mask disposal

- Waste disposal of the hood or replaceable mask, including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the “polluter pays principle”, and
- Transportation of the discarded hood or replaceable mask to the disposal or recycling site.

C4) Disposable battery disposal

- Waste disposal of the disposable battery(ies), including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the “polluter pays principle”, and
- Transportation of the discarded disposable battery(ies) to the disposal or recycling site.

C5) Cylinder disposal

- Waste disposal of the cylinder(s), including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the “polluter pays principle”, and
- Transportation of the discarded cylinder(s) to the disposal or recycling site.

Cx) Other replaceable elements disposal

- Waste disposal of the other replaceable element, including physical pre-treatment and management of the disposal site. Emissions from waste disposal are considered part of the product system under study and therefore are part of this module, according to the “polluter pays principle”, and
- Transportation of the discarded the other replaceable element to the disposal or recycling site.

4.3.2 INFRASTRUCTURE AND CAPITAL GOODS

In general, the production and end-of-life processes of infrastructure or capital goods²³ used in the product system should not be included within the system boundaries. They may be included when infrastructure and capital goods are known to be relevant in terms of their environmental impact, or when a generic LCI dataset includes infrastructure/capital goods, and it is not possible, within reasonable effort, to subtract the data on infrastructure/capital goods from this dataset. If an infrastructure/capital good is produced with the intention to be used one or a few times only (e.g., a manufacturing plant or machinery constructed to produce only one product), this infrastructure/capital good shall be included.

The inclusion or exclusion of infrastructure/capital goods shall be transparently described for upstream, core and downstream processes in the LCA report and in the EPD.

If infrastructure/capital goods are included, the following disclaimer shall be included in the results sections of the LCA report and in the EPD:

The results of the impact categories abiotic depletion of minerals and metals may be highly uncertain in LCAs that include capital goods/infrastructure in generic datasets, in case infrastructure/capital goods contribute greatly to the total results. This is because the LCI data of infrastructure/capital goods used to quantify these indicators in currently available generic datasets sometimes lack

²³ Examples of infrastructure and capital goods are the building in which the studied product or upstream materials or components are produced, machinery used in the manufacturing of the product or its materials or components, or vehicles used in transports in the product system. For example, if the EPD is on wind power, the power plant itself is considered the studied product and not infrastructure/capital goods. However, the buildings and machinery that make the wind turbine components are considered infrastructure/capital goods. Similarly, if the EPD is on a means of transport, the vehicle is considered the studied product and not infrastructure/capital goods.

temporal, technological and geographical representativeness. Caution should be exercised when using the results of these indicators for decision-making purposes.

4.3.3 OTHER BOUNDARY SETTING

4.3.3.1. Boundary towards nature

Boundaries to nature are defined as where the flows of material and energy resources leave nature and enter the technical system (i.e. the product system). Emissions cross the system boundary to nature when they are emitted to air, soil or water.

4.3.3.2. Boundary towards other technical systems

Boundaries towards other technical systems define the flow of materials and components to/from the product system under study and from/to other product systems. Processes of waste processing shall be assigned to the product system that generates the waste until the end-of-waste state is reached. The above outlined principle means that the generator of the waste shall carry the full environmental impact until the point in the product life cycle in which the end-of-waste criteria are fulfilled.

See Section 4.6 for further guidance.

4.3.3.3. Temporal boundary

The temporal boundary defines the time period for which the life cycle inventory data is recorded, e.g. for how long emissions from waste deposits are accounted. As default, the time period over which inputs to and outputs from the product system is accounted for shall be 100 years from the year that the LCA model best represents, considering the representativeness of the inventory data. This year shall, as far as possible, represent the year of the publication of the EPD.

4.3.3.4. Geographical boundary

The geographical boundary defines the geographical coverage of the LCA. This shall reflect the physical reality of the product under study, accounting for the representativeness of technology, input materials and input energy.

4.4 SYSTEM DIAGRAM

The system diagram changes depending on the type of RPD covered by the EPD and, for that reason, is not reported in this PCR. Table 3 in paragraph 4.3.1 shows the processes that are included in the product system. Additional information to create the RPD specific system diagram can be found in Annex A

A system diagram of the processes divided into life cycle stages shall be included in the LCA for the specific RPD and reported in the EPD.

4.5 CUT-OFF RULES

A cut-off rule of 1% shall be applied. In other words, the included inventory data (not including inventory data of processes that are explicitly outside the system boundary as described in Section 4.3) shall together give rise to at least 99% of the results of any of the environmental impact categories. Also, 99% of the mass of the product content and 99% of the energy use of the product life cycle shall be accounted for. The cut-off of inventory data should, however, be avoided, and all available inventory data shall be used.

The cut-off of inventory data, based on the above cut-off rule, should be an output of a sensitivity analysis, alone or in combination with expert judgment based on experience of similar product systems. Furthermore, the cut-off shall be possible to be verified in the verification process, hence the exclusion of inventory data based on the cut-off rule shall be documented in the LCA report, and the EPD developer shall provide the information the verifier considers necessary to verify the cut-off.

4.6 ALLOCATION RULES

Allocation can be divided into allocation of co-products, i.e. allocation of unit processes that generate several products, and allocation of waste, i.e. allocation of unit processes that generate materials that are, for example, landfilled recovered, recycled or reused, and which require further processing to cease being waste and become products (see criteria for end-of-waste state in Section 4.6.2).

The principles for allocation of co-products and allocation of waste are described separately in the following subsections.

4.6.1 CO-PRODUCT ALLOCATION

The following hierarchy of allocation methods shall be followed for co-product allocation:

1. Allocation shall be avoided, if possible, by dividing the process to be allocated into sub-processes and collecting the inventory data for each sub-process.
2. If allocation cannot be avoided, the inventory data should be partitioned between the different co-products in a way that reflects the underlying physical relationships between them, i.e. allocation should reflect the way in which the inventory data changes if the quantities of delivered co-products change.
3. If a physical relationship between the inventory data and the delivery of co-products cannot be established, the inventory data should be allocated between the co-products in a way that reflects other relationships between them. For example, inventory data might be allocated between co-products in proportion to their economic values. If economic allocation is used, a sensitivity analysis exploring the influence of the choice of the economic value shall be included in the LCA report.

4.6.2 ALLOCATION OF WASTE TREATMENT PROCESSES

Allocation of waste shall follow the polluter pays principle and its interpretation in EN 15804: "processes of waste processing shall be assigned to the product system that generates the waste until the end-of-waste state is reached." The end-of-waste state is reached when all the following criteria for the end-of-waste state are fulfilled (adapted from EN 15804):

- the recovered material, component or product is commonly used for specific purposes;
- a market or demand, identified e.g. by a positive economic value, exists for such a recovered material, component or product;
- the recovered material, component or product fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and
- the use of the recovered material, product or construction element will not lead to overall adverse environmental or human health impacts.

The above outlined principle means that the generator of the waste shall carry the full environmental impact until the point in the product life cycle in which the end-of-waste criteria are fulfilled. Waste may have a negative economic market value, and then the end-of-waste stage is typically reached after (part of) the waste processing and further refinement, at the point at which the waste no longer has a negative market value. This allocation method is (in most cases) in line with a waste generator's juridical and financial responsibilities. See the GPI for further information and examples.

4.7 DATA QUALITY REQUIREMENTS AND SELECTION OF DATA

Life cycle inventory data are classified into specific data and generic data, where the latter can be selected generic data or proxy data. The data categories are defined as follows:

- specific data (also referred to as "primary data" or "site-specific data"):
 - data gathered from the actual manufacturing plant where product-specific processes are carried out;
 - actual data from other parts of the life cycle traced to the product under study, for example site-specific data on the production of materials or generation of electricity provided by contracted suppliers, and transportation data on distances, means of transportation, load factor, fuel consumption, etc., of contracted transportation providers; and
 - LCI data from databases on transportation and energy where that is combined with actual transportation and energy parameters as listed above.
- generic data (sometimes referred to as "secondary data"), divided into:
 - selected generic data: data (e.g., commercial databases and free databases) that fulfil prescribed data quality requirements for precision, completeness, and representativeness (see below Section 4.7.1),
 - proxy data: data (e.g., commercial databases and free databases) that do not fulfil all of the data quality requirements of "selected generic data".

An overview of the data quality requirements per module is given in Table 4.

Table 4 Data quality requirements per module

MODULES	SPECIFIC DATA	GENERIC DATA
A1-A2	Mandatory when available	Optional
A3	Mandatory	Not allowed to be used
A4-A5	Recommended when available	Optional
B2-B5, Bx	Manufacturing in module: mandatory for same entity as main RPD system if under the control of the EPD owner, if not, mandatory when available Raw materials and transport in module: mandatory when available Distribution in module: recommended when available	Manufacturing in module: not allowed for same entity as main RPD system if under the control of the EPD owner, if not, optional Raw materials and transport in module: optional Distribution in module: optional
B1, C1-C5, Cx	Recommended when available	Optional

4.7.1 RULES FOR USING GENERIC DATA

For generic data to be classified as "selected generic data", the following requirements apply:

- datasets shall be based on attributional LCA modelling. They should neither be based on marginal data nor include credits from system expansion,
- the reference year shall be as current as possible and should be representative for the validity period of the EPD,
- the 1% cut-off rule (as described in Section A.3.3 of the GPI) shall be met on the level of the product system,
- datasets shall represent average values for a specific reference year. However, as data generation methodologies could vary, (e.g. over time) they should represent an annual average value for a specified reference period whereas deviations must be justified and declared in the EPD, and
- the representativeness of the data shall be assessed to be better than $\pm 5\%$ (in terms of the environmental impact calculated based on the data) of data that is fully representative for the given temporal, technological and geographical context.

If selected generic data meeting the above requirements are not available, proxy data may be used. The environmental impacts associated with proxy data shall not exceed 10% of the overall environmental impact of the product system.

The EPD should include a data quality declaration to demonstrate the share of specific, selected generic and proxy data contributing to the results of the environmental impact indicators.

4.7.2 EXAMPLES OF DATABASES FOR GENERIC DATA

No recommended databases for generic data have been identified for the product category since the PCR includes a large variety of RPD types and consequently a wide range of relevant databases. All commercial or publicly available datasets that fulfil the data quality requirements may be used. The specifications and the version of the database shall be reported in the EPD.

4.7.3 DATA QUALITY REQUIREMENTS AND OTHER MODELLING GUIDANCE PER LIFE-CYCLE STAGE

Additional data quality requirements per life-cycle stage are outlined below. Exceptions to the requirements may be accepted, if justified in the EPD. Such exceptions are subject to the approval by the verifier on a case-to-case basis.

4.7.3.1 Upstream processes

- Data referring to processes upstream in a supply chain over which the EPD owner has direct management control shall be specific and collected on site.

- Data referring to contractors that supply main parts, packaging, or main auxiliaries should be requested from the contractor as specific data, as well as infrastructure, where relevant.
- Data on transport of main parts and components along the supply chain to a distribution point (e.g. a stockroom or warehouse) where the final delivery to the manufacturer can take place, should be specific and based on the actual transportation mode, distance from the supplier, and vehicle load, if available.
- In case specific data is lacking, selected generic data may be used. If this is also lacking, proxy data may be used (see Section 4.7).
- For upstream processes modelled with specific data, generation of electricity used shall be accounted for in this priority:
 1. Specific electricity mix as generated, or purchased from an electricity supplier, demonstrated by a Guarantee of Origin or similar as provided by the electricity supplier.
 2. Residual electricity mix of the electricity supplier on the market.
 3. Residual electricity mix on the market²⁴.
 4. Electricity consumption mix on the market²⁵.

The residual electricity mix is the mix of all contract-specific electricity that has been sold to other customers and has been subtracted from the total consumption mix.

"The market" in the above hierarchy shall be defined as being the (residual or consumption) grid mix of the country where the electricity is used. Exceptions for which a sub-national electricity grid mix shall be used include Australia, Brazil, Canada, China, India, and USA.

The mix of electricity used in upstream processes shall be documented in the EPD, where relevant.

- Packaging: specific data shall be used for production of consumer²⁶ packaging if the production is under the direct control of the EPD owner or if the environmental impact of the production is more than 10% of the declared results in any of the environmental performance indicators. Otherwise, generic data may be used. When consumer packaging shows the organization's logo, the LCA report should state the exerted/non-exerted direct control on the production of consumer packaging by the organization.

4.7.3.2. Core processes

- Transport from the final delivery point of raw materials, chemicals, main parts, and components (see above regarding upstream processes) to the manufacturing plant/place of service provision should be based on the actual transportation mode, distance from the supplier, and vehicle load, if available.
- Specific data shall be used for the assembly of the product and for the manufacture of main parts as well as for on-site generation of steam, heat, electricity, etc., where relevant.
- For electricity used in the core processes, generation of electricity used shall be accounted for in this priority:
 1. Specific electricity mix as generated, or purchased from an electricity supplier, demonstrated by a Guarantee of Origin or similar as provided by the electricity supplier.
 2. Residual electricity mix of the electricity supplier on the market.
 3. Residual electricity mix on the market²⁷.

²⁴ The composition of the residual grid mixes on the market are available for all EU countries and a few additional European countries through the Association for Issuing Bodies (AIB) at <https://www.aib-net.org/facts/european-residual-mix>.

²⁵ For electricity markets without trade of Guarantees of Origin (or similar), the residual mix will, however, be identical to the consumption mix.

²⁶ Leaflets and user instructions are considered product packaging, but not consumer packaging.

²⁷ The composition of the residual grid mixes on the market are available for all EU countries and a few additional European countries through the Association for Issuing Bodies (AIB) at <https://www.aib-net.org/facts/european-residual-mix>.

4. Electricity consumption mix on the market²⁸. This option shall not be used for electricity used in processes over which the manufacturer (EPD owner) has direct control, as long as the composition of the residual grid mix has been publicly disclosed²⁹.

The residual electricity mix is the mix when all contract-specific electricity that has been sold to other customers has been subtracted from the total consumption mix.

"The market" in the above hierarchy shall be defined as being the (residual or consumption) grid mix of the country where the electricity is used, with exceptions for specified countries for which a sub-national electricity grid mix shall be used: Australia, Brazil, Canada, China, India, and USA.

The mix of electricity used in the core processes shall be documented in the EPD, where relevant.

- Waste treatment processes of manufacturing waste should be based on specific data, if available.
- Process emissions from manufacturing should be based on specific data, if available.

4.7.3.3. Downstream processes

- The above rules as described in Section 4.7.3.1 and 4.7.3.2 shall be followed for the raw materials and manufacturing processes of the filter(s), hood(s) or replaceable mask(s), disposable battery(ies), cylinders, and other replaceable elements when respectively relevant and when the EPD owner has direct management control of the manufacturing processes of the replaceable element(ies).
- When the manufacturing of the filter(s), hood(s) or replaceable mask(s), disposable battery(ies), cylinders, and other replaceable elements are not under direct control of the EPD owner, generic data representing the relevant product(s) can be used. However, specific data should be used when available and relevant. Key assumptions shall be documented in the EPD.
- The use of electricity (for charging the battery or running the compressor) in the region/country where the product is used (as specified in the geographical scope of the EPD) shall be accounted for in the following priority:
 1. Residual electricity mix on the market³⁰.
 2. Electricity consumption mix on the market³¹.

The residual electricity mix is the mix when all contract-specific electricity that has been sold to other customers has been subtracted from the total production mix.

"The market" in the above hierarchy shall be defined as being the (residual or consumption) grid mix of the country where the electricity is used, with exceptions for specified countries for which a sub-national electricity grid mix shall be used: Australia, Brazil, Canada, China, India, and USA.

The mix of electricity used in the downstream processes shall be documented in the EPD, where relevant.

- The transport of the product to the customer shall be described in the EPD, where relevant, and be accounted for in this priority:
 1. Actual transportation modes and distances to a specific customer or market, representing the geographical scope of the EPD.
 2. A weighted average of transportation modes and distances, based on transportation to several customers or markets, representing the geographical scope of the EPD.
 3. A default transportation scenario of relevance to the product category and (for the product category) common markets, as specified in the PCR.

²⁸ For electricity markets without trade of Guarantees of Origin (or similar), the residual mix will, however, be identical to the consumption mix.

²⁹ If the composition of the residual grid mix has not been publicly disclosed, the second or third options in the above hierarchy are not feasible and thus the fourth option is the only remaining option (if the first option is not chosen).

³⁰ The composition of the residual grid mixes on the market are available for all EU countries and a few additional European countries through the Association for Issuing Bodies (AIB) at <https://www.aib-net.org/facts/european-residual-mix>.

³¹ For electricity markets without trade of Guarantees of Origin (or similar), the residual mix will, however, be identical to the consumption mix.

- Scenarios for packaging disposal and the end-of-life stage shall be technically and economically practicable and compliant with current regulations in the relevant geographical region based on the geographical scope of the EPD. Key assumptions regarding the end-of-life stage scenario shall be documented in the LCA report.

4.7.4 DATA QUALITY DECLARATION

EPDs may include a declaration of the quality of data used in the LCA calculations.

4.8 ENVIRONMENTAL PERFORMANCE INDICATORS

The EPD shall declare the default environmental performance indicators and their methods as described at the website (www.environdec.com/indicators), which includes both inventory indicators and indicators of potential environmental impact. The source and version of the impact assessment methods and characterisations factors used shall be reported in the EPD. Also other indicators may be declared, if justified, see Section 5.4.5.

If the default list of environmental performance indicators and methods at the www.environdec.com/indicators is updated, the previous version of the list is valid in parallel to the new version during a transition period of at least 90 days, as described at the website.

Apart from inventory indicators (such as the required and optional inventory indicators listed at <https://www.environdec.com/indicators>), other inventory data may also be declared in the EPD, if relevant and useful for EPD users. Such data shall not be declared in the main body of the EPD, but in an annex.

4.9 INCLUDING MULTIPLE PRODUCTS IN THE SAME EPD

4.9.1 MULTIPLE PRODUCTS FROM THE SAME COMPANY

Several sets of results, reflecting different products, shall not be declared in the same EPD. However, similar products may be grouped and thereby included in the same EPD under one set of results. Similar products are defined as products covered by the same PCR, with identical or similar functions, manufactured by a single company at one or several manufacturing sites, with the same major steps in the A3/core processes. For such an EPD, there are three options:

- For each indicator, declare the average results of the included products. This average shall be weighted according to the production volumes of the included products, if relevant. In this option, the average content shall be declared in the content declaration.
- Declare the results of one of the included products or the average of a subset of the included products, i.e., one or several representative products. The choice of the representative product(s) shall be justified in the EPD, for example based on production volumes. In this option, the content of the representative product, or the average of the representative products, shall be declared in the content declaration.
- For each indicator and module A-C, declare the highest result of the included products. This option thus corresponds to the results of a "worst-case product", which may consist of results from one or several of the included products. In this option, the content declaration shall include the lowest amounts of recycled and biogenic content of the included products and their packaging, respectively, and the information on environmental and hazardous properties of substances shall reflect the highest share and most hazardous such substances contained in the any of the included products.

For all options, the range of the content of the included products should be included in the content declaration, in addition to the average/representative/worst-case content as specified above.

In the EPD, variations in the declared environmental impact indicator results (aggregated over all included modules (from A to C)) above 10% are allowed. In such cases, the LCA report shall include an explanation of the variation and a justification of the grouping of products, and the EPD shall (in the LCA information section) declare the variation of each impact indicator results for which the variation is above 10% and include an explanation of the variation. EPDs based on worst-case results are exempted from the requirement to declare the variation if above 10%.

The option chosen shall be clearly described at the cover page of the EPD, as "EPD of multiple products, based on the average results of the product group", "EPD of multiple products, based on a representative product", "EPD of multiple products, based on several representative products", or "EPD of multiple products, based on worst-case results".

In an EPD of multiple products based on worst-case results, the lowest GWP-total results of the included products may be optionally reported in a subsection of the environmental performance section, and the content declaration of the “best-case product” may be optionally reported in a subsection of the content declaration section.

Note that above paragraphs concern grouping of similar products, but not grouping of identical products (e.g., produced at different manufacturing sites or at different production lines at one site). Identical products here refer to products which are not marketed as different products and/or are in no other way distinguishable by a downstream customer.³² For identical products, variations due to, for example, manufacturing at several sites shall be treated as any other variation in production, by averaging over (normally) one year of production (and in such cases, variations above 10% are also allowed).

Although a variation above 10% is allowed in EPDs of identical products manufactured at several sites, it is recommended to separate the EPDs per site so that a variation below 10% is met, as certain national regulation considers an EPD to be “product-specific” only when the variation between sites is below 10%.

4.9.2 SECTOR EPDS

The International EPD® System allows for an industry association to develop an EPD in the form of a Sector EPD. A Sector EPD declares the average product of multiple companies in a clearly defined sector in a clearly defined geographical area. Products covered in a sector EPD shall follow the same PCR and the same declared/functional unit shall be applied.

Any communication of the results from a Sector EPD should contain the information that the results are based on averages obtained from the sector as defined in the EPD. The communication shall not claim that the sector EPD results are representative for a certain manufacturer or its product.

The following information shall also be included in a Sector EPD:

- a list of the contributing manufacturers that the Sector EPD covers,
- a description of how the selection of the sites/products has been done and how the average has been determined, and
- a statement that the document covers average values for an entire or partial product category (specifying the percentage of representativeness) and, hence, the declared product is an average that is not available for purchase on the market.

³² This means that product variations that are different with regard to colour, content, size, configurations, or similar, normally shall be considered to be similar, and not identical, products.

5 CONTENT AND FORMAT OF EPD

EPDs based on this PCR shall contain the information described in this section. Flexibility is allowed in the formatting and layout provided that the EPD still includes the prescribed information. A generic template for EPDs is available at www.environdec.com.

The EPD content shall:

- be in line with the requirements and guidelines in ISO 14020 (Environmental labels and declarations – General principles),
- be verifiable, accurate, relevant and not misleading, and
- not include rating, judgements or direct comparison with other products³³.

An EPD should be made with a reasonable number of pages for the intended audience and use.

The content of EPDs published in machine-readable format shall correspond with the content of the underlying EPD.

5.1 EPD LANGUAGES

EPDs should be published in English but may also be published in additional languages. If the EPD is not available in English, it shall contain an executive summary in English including the main content of the EPD. This summary is part of the EPD and, thus, also subject to the verification process.

5.2 UNITS AND QUANTITIES

The following requirements apply for units and quantities:

- The International System of Units (SI units) shall be used where available, e.g., kilograms (kg), Joules (J) and metres (m). Reasonable multiples of SI units may be decided in the PCR to improve readability, e.g., grams (g) or megajoules (MJ). The following exceptions apply:
 - Resources used for energy input (primary energy) should be expressed as kilowatt-hours (kWh) or megajoules (MJ), including renewable energy sources, e.g., hydropower, wind power and geothermal power.
 - Water use should be expressed in cubic metres (m³)
 - Temperature should be expressed in degrees Celsius (°C),
 - Time should be expressed in the units most practical, e.g., seconds, minutes, hours, days or years.
 - Results of the environmental performance indicators shall be expressed in the units prescribed by the impact assessment methods, e.g. kg CO₂ equivalents.
- Three significant figures³⁴ should be adopted for all results. The number of significant digits shall be appropriate and consistent.
- Scientific notation may be used, e.g. 1.2E+2 for 120, or 1.2E-2 for 0.012.
- The thousand separator and decimal mark in the EPD shall follow one of the following styles (a number with six significant figures shown for illustration):
 - SI style (French version): 1 234,56
 - SI style (English version): 1 234.56

In case of potential confusion or intended use of the EPD in markets where different symbols are used, the EPD shall state what symbols are used for thousand separator and decimal mark.

- Dates and times presented in the EPD should follow the format in ISO 8601. For years, the prescribed format is YYYY-MM-DD, e.g., 2017-03-26 for March 26th, 2017.

³³ Therefore, results of normalization are not allowed to be reported in the EPD.

³⁴ Significant figures are those digits that carry meaning contributing to its precision. For example with two significant digits, the result of 123.45 shall be displayed as 120, and 0.12345 shall be displayed as 0.12. In scientific notation, these two examples would be displayed as 1.2*10² and 1.2*10⁻².

- The result tables shall:
 - Only contain values or the letters “ND” (Not Declared). It is not possible to specify ND for mandatory indicators. ND shall only be used for voluntary parameters that are not quantified because no data is available.³⁵
 - Contain no blank cells, hyphens, less than or greater than signs or letters (except “ND”).
 - Use the value “0” only for parameters that have been calculated to be zero.
 - Footnotes shall be used to explain any limitation to the result value.

5.3 USE OF IMAGES IN EPD

Images used in the EPD, especially pictures featured on the cover page, may in themselves be interpreted as an environmental claim. Images such as trees, mountains, wildlife that are not related to the declared product shall therefore be used with caution and in compliance with national legislation and best available practices in the markets in which the EPD is intended to be used.

5.4 EPD REPORTING FORMAT

The reporting format of the EPD shall include the following sections:

- Cover page (see Section 5.4.1)
- Programme information (see Section 5.4.2)
- Product information (see Section 5.4.3)
- Content declaration (see Section 5.4.4)
- Environmental performance (see Section 5.4.5)
- References (see Section 5.4.9)

The following sections may be included:

- Additional environmental information (see Section 5.4.6)
- Additional social and economic information (see Section 5.4.7)

The following sections shall be included, if relevant:

- Differences versus previous versions (see Section 5.4.8)
- Executive summary in English (see Section 5.4.10)

5.4.1 COVER PAGE

The cover page shall include:

- Product name and image
- Name and logotype of EPD owner
- The text “Environmental Product Declaration” and/or “EPD”
- Programme: The International EPD[®] System, www.environdec.com
- Programme operator: EPD International AB
- Logotype of the International EPD[®] System
- EPD registration number as issued by the programme operator³⁶

³⁵ This requirement does not intend to give guidance on what indicators are mandated (“shall”) or voluntary.

³⁶ The EPD shall not include a “registration number” if such is provided by the certification body, as this may be confused with the registration number issued by the programme operator.

RESPIRATORY PROTECTIVE DEVICES
PRODUCT CATEGORY CLASSIFICATION: MULTIPLE UN CPC

- Date of publication (issue): 20XX-YY-ZZ
- Date of revision: 20XX-YY-ZZ, when applicable
- Date of validity: 20XX-YY-ZZ
- A note that “An EPD should provide current information and may be updated if conditions change. The stated validity is therefore subject to the continued registration and publication at www.environdec.com.”
- A statement of conformity with ISO 14025.
- For EPDs covering multiple products: a statement that the EPD covers multiple products and a list of all products covered by the EPD.
- For Sector EPDs: a statement that the EPD is a Sector EPD.

In the case of EPDs registered through a regional hub (a regional or national programme based on and fully aligned with the International EPD® System through an agreement with the programme operator), “Programme”, “Programme operator”, and “Logotype” shall be expanded to include a reference to the regional programme and the organisation responsible for it.

Where applicable, the cover page shall also include the following information:

- Information about dual registration of EPD in another programme, such as registration number and logotype.
- A statement of conformity with other standards and methodological guides.

5.4.2 PROGRAMME INFORMATION

The programme information section of the EPD shall include:

- Address of programme operator: EPD International AB, Box 210 60, SE-100 31 Stockholm, Sweden, E-mail: info@environdec.com
- The following statement on the requirements for comparability of EPDs, adapted from ISO 14025: “EPDs within the same product category but from different programmes may not be comparable. For two EPDs to be comparable, they must be based on the same PCR (including the same version number) or be based on fully aligned PCRs or versions of PCRs; cover products with identical functions, technical performances and use (e.g. identical declared/functional units); have equivalent system boundaries and descriptions of data; apply equivalent data quality requirements, methods of data collection, and allocation methods; apply identical cut-off rules and impact assessment methods (including the same version of characterisation factors); have equivalent content declarations; and be valid at the time of comparison.”
- A statement that the EPD owner has the sole ownership, liability and responsibility of the EPD
- Information about verification³⁷ and the PCR in a table with the following format and contents:

Accountabilities for PCR, LCA and independent, third-party verification
Product Category Rules (PCR)
PCR: <name, registration number, version and UN CPC code(s)>
PCR review was conducted by: <name and organisation of the review chair, and information on how to contact the chair through the programme operator>
Life cycle assessment (LCA)
LCA accountability: <name, organization>
Third-party verification

³⁷ If the EPD has been verified by an approved individual verifier who has received contractual assistance from a certification body that is not accredited, this certification body shall not be included in this table.

Independent third-party verification of the declaration and data, according to ISO 14025:2006, via: ☐ EPD verification by individual verifier Third-party verifier: <i><name, organisation, and signature of the third-party verifier></i> Approved by: The International EPD® System
OR
Independent third-party verification of the declaration and data, according to ISO 14025:2006, via: ☐ EPD verification by accredited certification body Third-party verification: <i><name, organisation></i> is an approved certification body accountable for the third-party verification The certification body is accredited by: <i><name of accreditation body & accreditation number, where applicable></i>
OR
Independent third-party verification of the declaration and data, according to ISO 14025:2006 via: ☐ EPD verification by EPD Process Certification* Internal auditor: <i><name, organisation></i> Third-party verification: <i><name, organisation></i> is an approved certification body accountable for third-party verification Third-party verifier is accredited by: <i><name of accreditation body & accreditation number, where applicable></i> *For EPD Process Certification, an accredited certification body certifies and reviews the management process and verifies EPDs published on a regular basis. For details about third-party verification procedure of the EPDs, see GPI v4, Section 7.5. Procedure for follow-up of data during EPD validity involves third-party verifier³⁸: ☐ Yes ☐ No

5.4.3 PRODUCT INFORMATION

The product information section of the EPD shall include:

- address and contact information of the EPD owner,
- description of the organisation. This may include information on products- or management system-related certifications (e.g. ISO 14024 Type I environmental labels, ISO 9001- and 14001-certificates and EMAS-registrations) and other relevant work the organisation wants to communicate (e.g. SA 8000, supply-chain management and social responsibility),
- name and location of production site,

³⁸ Procedure for follow-up the validity of the EPD is at minimum required once a year with the aim of confirming whether the information in the EPD remains valid or if the EPD needs to be updated during its validity period (see Sections 7.3.2 and 7.4.9 of the GPI). The follow-up can be organized entirely by the EPD owner or together with the original verifier via an agreement between the two parties. In both approaches, the EPD owner is responsible for the procedure being carried out. If a change that requires an update (see Section 6.5 of the GPI) is identified, the EPD shall be re-verified by a verifier.

RESPIRATORY PROTECTIVE DEVICES
PRODUCT CATEGORY CLASSIFICATION: MULTIPLE UN CPC

- product identification by name, and an unambiguous identification of the product by standards, concessions or other means,
- identification of the product according to the UN CPC scheme system, if applicable. Other relevant codes for product classification may also be included, e.g.
 - Common Procurement Vocabulary (CPV),
 - United Nations Standard Products and Services Code® (UNSPSC),
 - Classification of Products by Activity (NACE/CPA),
 - Australian and New Zealand Standard Industrial Classification (ANZSIC), or
 - Global Trade Item Number (GTIN).
- a description of the product,
- a description of the technical purpose/function of the product, including its application/intended use. At the least the following technical performance indicators, if relevant for the type of respirator shall be given:
 - Type of respirator
 - Filter media type (if applicable)
 - Regulatory classification (e.g. FFP3, N95, TH3)
 - Type of mask or hood (if applicable)
 - Type of exhalation valve (if applicable)
 - Type of harness or straps (if applicable)
 - Type of battery and battery life (if applicable)
 - Type of air supply (if applicable)
- a description of the background system, including the main technological aspects,
- for EPDs covering multiple products: a description of the selection of products/sites, a list of contributing manufacturers (if Sector EPD), etc. (see Section 4.9),
- geographical scope of the EPD, i.e., for which geographical location(s) of use and end-of-life the product's performance has been calculated,
- declared unit,
- declaration of the year(s) covered by the data used for the LCA calculation and other relevant reference years,
- reference to the main database(s) for generic data and LCA software used, if relevant, system diagram of the processes included in the LCA, divided into the life cycle stages and information modules as defined in Section 4.3.1. This diagram should also describe geography, specific data and variation in GWP results products and sites. See
-
- Table 5 for an example,
- information on which life-cycle stages are not considered (if any), with a justification of the omission,
- any additional information about the underlying LCA-based information, such as cut-off rules, data quality, allocation methods, and other methodological choices and assumptions, and
- references to any relevant websites for more information or explanatory materials.

This section may also include:

- name and contact information of organisation carrying out the underlying LCA study,
- a statement that the EPD shall not be used for communicating environmental information to consumers/end users if end-of-life treatment is not included.

Table 5 Example for the reporting of modules declared, geographical scope, share of specific data (in GWP results) and variation in GWP results between products and sites

Life cycle phase	Upstream	Core		Downstream													
Life cycle module group	Product stage			Distribution stage		Use stage						End of life stage					
Life cycle module name	Raw material supply	Transportation	Manufacturing	Transportation	Waste treatment of distribution packaging	Waste treatment of main RPD system packaging	Filters	Hoods or replaceable masks	Battery power supply	Air supply	(Other replaceable elements)	Main RPD system disposal	Filter disposal	Hood or replaceable mask disposal	Disposable battery disposal	Cylinder disposal	(Other replaceable elements disposal)
Module	A1	A2	A3	A4	A5	B1	B2	B3	B4	B5	(Bx)	C1	C2	C3	C4	C5	(Cx)
Modules declared																	
Geography																	
Specific data used				-	-	-						-	-	-	-	-	-
Variation - products				-	-	-						-	-	-	-	-	-
Variation - sites				-	-	-						-	-	-	-	-	-

Guidance for filling in

Table 5 (this guidance shall be followed also if

Table 5 is not used as a template for reporting this data):

- Modules declared:
 - Modules declared shall be noted with "X".
 - Modules not declared shall be marked as "ND".
- Modules Bx and Cx are only required to be reported when another replaceable element is present in the RPD.
- Geography:
 - Geographical representation per module shall be reported. This reporting shall be done by the country code(s) (e.g. UK, FR, DE) and/or name of the region(s) (e.g. EU 28, Global).
- Specific data used:
 - The share of the GWP results in A1-A3, and B2-B5, (Bx) if relevant, coming from product-specific LCI data shall be reported in the EPD. If more than 90% specific data is used in the EPD, ">90%" may be reported.
 - Specific data is here defined as:
 - data gathered from the actual manufacturing plant where product-specific processes are carried out;
 - actual data from other parts of the life cycle traced to the product under study. Examples include site-specific data on the production of materials or generation of electricity provided by contracted suppliers, and transportation data on distances, means of transportation, load factor, fuel consumption of contracted transportation providers; and

- LCI data from databases on transportation and energyware that are combined with actual transportation and energy parameters as listed above.
 - All other data is regarded as proxy data or data that can be proven to be conservative.
 - Note that the above definition of proxy data differs from the definition in the GPI. When the EPD uses another EPD as a data source, it may not be possible to calculate the percentage of product specific LCI data (for example if the other EPD has not reported this percentage, or the underlying LCA data cannot be accessed). If this is the case, an expert judgment on the amount of specific data may be made based on the information available in the EPD used as data source. If a larger share than 60% is estimated by this simplified approach, it shall be stated in the EPD that "The percentage of specific data is assumed to be larger than 60%, but it cannot be proved since one or several EPDs that are used as data sources lack information on the percentage of specific data used."
- Variation – products:
 - If the EPD is based on multiple, similar products, the difference in GWP results for modules A1-A3, and B2-B5, (Bx) if relevant, between the reported result and the results for the underlying products shall be reported in percentage, if the variation is above 10%. If the variation is below 10%, the actual variation or "<10%" shall be reported. If the results are for one product, "0%" shall be declared.
 - Variation – sites:
 - If the EPD is based on multiple manufacturing sites, the difference in GWP results for modules A1-A3, and B2-B5, (Bx) if relevant, between the reported result and the results for the underlying sites shall be reported in percentage, if the variation is above 10%. If the variation is below 10%, the actual variation or "<10%" shall be reported. If the results are for one manufacturing site, "0%" shall be declared.

5.4.4 CONTENT DECLARATION

The content declaration section shall declare the weight of one unit of product, as purchased. It should contain information about the content of the product in the form of a list of materials and chemical substances, including information on their environmental and hazardous properties. The gross weight of each material/substance shall be declared, including a minimum of 99% of the materials/substances in one unit of product.

The content declaration does not apply to proprietary materials and substances covered by exclusive legal rights including patent and trademarks. In general, an indication that a product is "free" of a specific hazardous material or substance should be done with caution and only when relevant, following the rules in ISO 14021 on self-declared environmental claims.

Information on the hazardous properties of materials and chemical substances should follow the requirements given in the latest revision of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS),³⁹ issued by the United Nations or national or regional applications of the GHS. As an example, the following regulations should be used for EPDs intended to be used in the European Union:

- Regulation (EC) No 1907/2006 of the European parliament and of the council of 18 December 2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH); and
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures.

5.4.4.1 Information about recycled materials

When a product is made in whole or in part with recycled materials, the provenance of the materials (pre-consumer or post-consumer) shall be presented in the EPD as part of the content declaration.

To avoid any misunderstanding about which material that may be considered "recycled material", the guidance given in ISO 14021 shall be considered. In brief, the standard states that:

- only pre-consumer or post-consumer materials (scraps) shall be considered in the accounting of the recycled materials, and
- materials coming from scrap reutilisation (such as rework, regrind, or scrap generated in a process and capable of being reclaimed within the same process that generated it) shall not be considered as recycled content.

³⁹ The GHS document is available at www.unece.org.

5.4.4.2. Information about packaging

As packaging is strongly connected with the product, the producer shall provide information about packaging in the EPD, when applicable. Packaging may be classified as:

- Distribution Packaging: packaging designed to contain one or more articles or packages, or bulk materials, for the purposes of transport, handling and/or distribution (ISO 21067-1:2016, Section 2.2.6)
- Consumer Packaging: packaging constituting, with its contents, a sales unit for the final user or consumer at the point of retail (ISO 21067-1:2016, Section 2.2.7).

Consumer packaging is generally the outcome of eco-design processes, or other activities, under direct control of the organisation. Many critical categories with strict legal requirements belong to consumer packaging category like food contact packaging and pharmaceutical packaging.

The weight (per product), type and function of the packaging shall be reported in the EPD.

A statement of the source of the materials (pre-consumer or post-consumer) shall be presented in the EPD when the packaging is made in whole or in part with recycled materials.

At the minimum, the following information shall be given as presented in Table 6 below. A more detailed example is given in Annex B.

Table 6 Example of content declaration

MATERIAL	WEIGHT [kg]	WEIGHT [wt%]	RECYCLED CONTENT [wt%]
Polypropylene	0.225	45%	0%
Silicone rubber	0.185	37%	0%
Aluminium	0.010	2%	100%
Carbon black	0.080	16%	0%
Total	0.500	100%	2%
PACKAGING MATERIAL	WEIGHT FOR 1 RPD [kg]	FUNCTION	RECYCLED CONTENT [wt%]
Polyethylene bag	0.010	Consumer packaging	70%
Cardboard box	0.010	Consumer packaging	50%
Paper	0.020	User instructions	0%
Shipper cardboard box	0.010	Distribution packaging	100%
Pallet	0.083	Distribution packaging	0%
Total	0.133	N/A	17%

5.4.5 ENVIRONMENTAL PERFORMANCE

Below subsections list the mandatory environmental performance indicators to declare in the EPD. LCA results based on additional indicators may be declared, if they are relevant for the product category, their inclusion is justified in the EPD, appropriate methods⁴⁰ are used, and the results are verifiable. If the additional indicators appear to the reader to display duplicate information, the EPD shall contain an explanation of the differences between the declared indicators.

The EPD shall include the following statement in the Environmental performance section: *Comparisons of EPDs of different respiratory protective devices shall only be done if the products perform the same function. If the results of different EPDs are recalculated for a*

⁴⁰ If any of the following impact categories are declared in the EPD, the corresponding characterisation methods listed in EN 15804 should be used: particulate matter emissions, ionizing radiation (human health), eco-toxicity (freshwater), human toxicity (cancer effects), human toxicity (non-cancer effects) and land use related impacts/soil quality. If these impact categories and characterisation methods are used, the corresponding disclaimers listed in EN 15804 shall be declared in the EPD.

certain use scenario, the rules in Annex C of the PCR shall be used. Such use scenarios shall include an estimated technical lifespan and should follow the manufacturer's instructions for use, inspection, maintenance, and, where applicable, routine servicing.

5.4.5.1. Environmental impacts

The EPD shall declare the environmental impact indicators, per declared unit, per life-cycle stage and in aggregated form, using the default impact categories, impact assessments methods and characterisation factors available at www.environdec.com/indicators. The source and version of the impact assessment methods and characterisation factors used shall be reported in the EPD.

The environmental impact indicators, associated with each of the modules considered (from A1 to C5, Bx and Cx if relevant), shall be reported separately. The environmental performance results of individual information modules shall not be added up into any combination into a total or sub-total of the lifecycle stages A, B or C.

Alternative regional life cycle impact assessment methods and characterisation factors may be calculated and displayed in addition to the default list. If so, the EPD shall contain an explanation of the differences between the declared sets of indicators, as they may appear to the reader to display duplicate information.

5.4.5.2. Use of resources

The EPD shall declare the mandatory, and may declare the optional, indicators for resource use listed at <https://www.environdec.com/indicators> per declared unit, per life-cycle stage and in aggregated form.

The environmental impact indicators, associated with each of the modules considered (from A1 to C5, Bx and Cx if relevant), shall be reported separately. The environmental performance results of individual information modules shall not be added up into any combination into a total or sub-total of the lifecycle stages A, B or C.

5.4.5.3. Waste production and output flows

Waste generated along the whole life cycle production chains shall be treated following the technical specifications described in the GPI. The EPD may declare the optional indicators for waste production and output flows as listed at <https://www.environdec.com/indicators> per declared unit, per life-cycle stage and in aggregated form.

The environmental impact indicators, associated with each of the modules considered (from A1 to C5, Bx and Cx if relevant), shall be reported separately. The environmental performance results of individual information modules shall not be added up into any combination into a total or sub-total of the lifecycle stages A, B or C.

5.4.6 ADDITIONAL ENVIRONMENTAL INFORMATION

An EPD may declare additional environmentally relevant information, in addition to the LCA results of the section on environmental performance results. The additional environmental information may cover various aspects of specific relevance for the product, for example:

- the release of dangerous substances into indoor air, soil, and water during the use stage,
- instructions for proper use of the product, e.g. to minimise energy or water consumption or to improve the durability of the product,
- instructions for proper maintenance and service of the product, e.g. to minimise energy or water consumption or to improve the durability of the product,
- information on key parts of the product that determine its durability,
- information on recycling including, e.g. suitable procedures for recycling the entire product or selected parts and the potential environmental benefits gained,
- information on a suitable method of reuse of the product (or parts of the products) and procedures for disposal as waste at the end of its life cycle,
- information regarding disposal of the product, or inherent materials, and any other information considered necessary to minimise the product's end-of-life impacts, and
- a more detailed description of an organisation's overall environmental work, in addition to the information listed under Section 5.4.3, such as:

- the existence of any type of organised environmental activity, and
- information on where interested parties may find more details about the organisation's environmental work.

Any additional environmental information declared shall be substantiated and verifiable, and be derived using appropriate methods and be specific, accurate, not misleading, and relevant to the specific product. Quantitative information is preferred over qualitative information.

The additional environmental information shall not include LCA results, with some exceptions:

- If the EPD owner wants to display results of several scenarios for use or end-of-life stages, the most representative scenario (for the geographical scope of the EPD) shall be declared in the section on environmental performance results, and the other scenarios shall be declared in the section on additional environmental information.
- The LCA results of an alternative modelling approach may be declared as additional environmental information, if such an alternative modelling approach is explicitly allowed by the applicable PCR or the GPI. According to this PCR, alternative GWP-biogenic results may be declared, which considers the effect of long-term storage of biogenic carbon (see next bullet point).
- The additional environmental information may include information on permanent (more than 100 years) storage of biogenic carbon, either in the product, in a landfill, or as a consequence of applying carbon capture and storage (CCS) to the incineration of biogenic carbon, and how this would influence GWP-biogenic results if the GWP-biogenic indicator would allow consideration of such storage.
- The environmental results based on an optional functional unit of 1 cycle of use may be reported for reusable RPDs by rescaling the given components based on their individual specified technical lifespan. The environmental performance related to this functional unit shall be reported as additional environmental indicators under the additional information and the EPD shall contain an explanation of the difference between the different sets of indicators, as they may appear to the reader to display duplicate information. See Section 4.1.1.

5.4.7 ADDITIONAL SOCIAL AND ECONOMIC INFORMATION

The EPD may also include other relevant social and economic information as additional and voluntary information. This may be product information or a description of an organisation's overall work on social or economic sustainability, such as activities related to supply chain management or social responsibility.

Any additional social and economic information declared shall be substantiated and verifiable, and be derived using appropriate methods and be specific, accurate, not misleading, and relevant to the specific product. Quantitative information is preferred over qualitative information.

5.4.8 DIFFERENCES VERSUS PREVIOUS VERSIONS

For EPDs that have been updated, the following information shall be included:

- a description of the differences versus previously published versions, and
- a revision date on the cover page.

5.4.9 REFERENCES

A reference section shall be included, including a list of all sources referred to in the EPD, including the GPI (including version number), and PCR (registration number, name, and version) used to develop the EPD.

5.4.10 EXECUTIVE SUMMARY IN ENGLISH

The executive summary, if included (see Section 5.1), shall contain relevant summarised information related to the programme, product, environmental performance, information related to pre-certified EPDs, and information related to sector EPDs. Besides this, further information may be added such as additional environmental, social or economic information, references as well as differences versus previous EPD versions.

6 LIST OF ABBREVIATIONS

AIB	Association for Issuing Bodies
ANZSIC	Australian and New Zealand Standard Industrial Classification
CEN	European Committee for Standardization
CFR	Code of federal regulations
CPC	Central product classification
CPV	Common procurement vocabulary
DE	Germany
EMAS	Eco-management and audit scheme
EN	European norm
EPD	Environmental product declaration
EU	European Union
FFP	Filtering facepiece
FFR	Filtering Facepiece Respirator
FR	France
GHS	Globally harmonized system
GPI	General Programme Instructions
GTIN	Global trade item number
GWP	Global warming potential
IBU	Institut Bauen und Umwelt e.V
ISO	International Organization for Standardization
LCA	Life cycle assessment
LCI	Life cycle inventory
NACE/CPA	Classification of products by activity
ND	Not declared
OSHA	Occupational Safety and Health Administration
PAPR	Powered air-purifying respirator
PCR	Product category rules
PEP	Product Environmental Profile
REACH	Restriction of chemicals
RPD	Respiratory protective device
RSL	Reference service life
SAR	Supplied air respirator
SCBA	Self-contained breathing apparatus
SI	The International System of Units
UK	United Kingdom
UN	United Nations

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UNSPSC	United Nations standard products and services code
USA	United States of America
wt%	Weight percentage

7 REFERENCES

CEN (2013) EN 15804:2012+A1:2013, Sustainability of construction works – Environmental product declarations – Core rules for the product category of construction products.

CEN (2019) EN 15804:2012+A2:2019, Sustainability of construction works – Environmental product declarations – Core rules for the product category of construction products.

CEN (2001) EN 149:2001+A1:2009, Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking.

Commission Regulation (EU) 2022/1998 of 20 September 2022 – Amendment Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff.

EN 529, Respiratory protective devices – Recommendations for selection, use, care, and maintenance Guidance Document.

EPD International (2021) General Programme Instructions for the International EPD® System. Version 4.0 dated 2021-03-29. www.environdec.com.

ISO (2000) ISO 14020:2000, Environmental labels and declarations – General principles.

ISO (2004) ISO 8601:2004 Data elements and interchange formats – Information interchange – Representation of dates and times.

ISO (2006a) ISO 14025:2006, Environmental labels and declarations – Type III environmental declarations – Principles and procedures.

ISO (2006b) ISO 14040:2006, Environmental management – Life cycle assessment – Principles and framework.

ISO (2006c) ISO 14044: 2006, Environmental management – Life cycle assessment – Requirements and guidelines.

ISO (2014) ISO 14046:2014, Environmental management – Water footprint – Principles, requirements and guidelines.

ISO (2015a) ISO 14001:2015, Environmental management systems – Requirements with guidance for use.

ISO (2015b) ISO 9001:2015, Quality management systems – Requirements.

ISO (2016a) ISO 21067-1:2016, Packaging – Vocabulary – Part 1: General terms.

ISO (2016b) ISO 14021:2016, Environmental labels and declarations - Self-declared environmental claim (Type II environmental labelling).

ISO (2017) ISO 21930:2017, Sustainability in buildings and civil engineering works – Core rules for environmental product declarations of construction products and services.

ISO (2018a) ISO 14024:2018, Environmental labels and declaration – Type I environmental labelling – Principles and procedures.

ISO (2018b) ISO/TS 14067:2018, Greenhouse gases – Carbon footprint of products – Requirements and guidelines for quantification and communication.

ISO (2020) ISO 16972:2020, Respiratory protective devices.

ISO (2022) ISO/TS 16975-4:2022, Respiratory protective devices — Selection, use and maintenance — Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease.

PCR 2017:01 (2023) v2.0, Disposable surgical drapes, gowns, air suits and face masks used for patients, clinical staff and equipment.

8 VERSION HISTORY OF PCR

VERSION 1.0.0, 2024-09-12

Original and first version of the PCR.

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ANNEX A – PRODUCT EXAMPLES

Table 7 Product examples with indication of possible materials of RPD

PRODUCT GROUP	PRODUCT TYPE	MAIN RPD SYSTEM (A1-A3)	POSSIBLE MATERIALS IN MAIN RPD SYSTEM (A1-A3)	REPLACEABLE COMPONENTS (B2-B5) ⁴¹	POSSIBLE MATERIALS IN REPLACEABLE COMPONENTS (B2-B5)
Single-Use RPDs	Filtering facepiece respirators	Facepiece, braid or strap, and valve (optional)	Non-woven synthetic material, such as polypropylene, plastic valve and elastic strap.	N/A	N/A
	Combined gas and vapours filtering facepiece	Facepiece, filtering media, braid or strap, and valve (optional)	Elastomeric interface including combined gas (e.g. carbon) /particle filters, plastic valve and elastic strap.	N/A	N/A
Passive reusable RPDs	Valved filtering half masks with particle filters	Facepiece, valve, strap, and filter	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Attached filters are typically made from glass fibre, or nonwoven materials. Strap can be made from an elastic or nylon.	N/A	N/A
	Valved filtering half masks with gas filters	Facepiece, valve, strap, and filter	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Attached filters are typically made from a hard plastic case with carbon granules. Strap can be made from an elastic or nylon.	N/A	N/A
	Valved filtering half masks with combination gas and particulate filters	Facepiece, valve, strap, and filter	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Attached filters are typically made from glass fibre, or nonwoven materials, as well as treated carbon, sometimes in a plastic case. Strap can be made from an elastic or nylon.	N/A	N/A
	Half facepiece respirators with particulate filters	Facepiece and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case (optional)	Replaceable filters are typically made from glass fibre, or nonwoven materials, sometimes in a plastic case.
	Half facepiece respirators with gas filters	Facepiece and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated.
	Half facepiece respirators with combination gas and particulate filters	Facepiece and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated. May have a glass fibre/non-woven particle filter included.

⁴¹ Other replaceable elements reported under Bx are not reported in this table

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	Full facepiece respirators with particulate filters	Facepiece, including visor and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case	Replaceable filters are typically made from glass fibre, or nonwoven materials, sometimes in a plastic case.
	Full facepiece respirators with gas filters	Facepiece, including visor and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated.
	Full facepiece respirators with combination gas particulate filters	Facepiece, including visor and strap	Mask is from soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon.	Filter (B2): filter material and case	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated. May have a glass fibre/non-woven particle filter included.
PAPRs	Power Assisted devices with hoods	Battery ⁴² and fan in hard plastic case Hose Belt or backpack	Fan unit contains battery, electronic, metal fan, encased in hard plastic case. Fan can be waist, back or head mounted. The hose is typically made of metalized plastic.	Filter (B2): filter material and case Hood (B3) Charging battery or disposable battery if relevant (B4)	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated. May have a glass fibre/non-woven particle filter included. Hoods can be made from lightweight coated fabric or nonwoven materials with transparent visor. Other hoods look like helmets with a visor, made from hard plastic, and foam parts. Different types of batteries, if relevant.
	Power Assisted devices with masks	Battery ⁴² and fan in hard plastic case Hose Belt or backpack	Fan unit contains battery, electronic, metal fan, encased in hard plastic case. Fan can be waist, back or head mounted. The hose is typically made of metalized plastic.	Filter (B2): filter material and case Mask ⁴³ (B3): facepiece, including visor and strap Charging battery or disposable battery if relevant (B4)	Replaceable filters are typically made from a plastic hardcase, with carbon granules inside. Sometimes the carbon granules are treated. May have a glass fibre/non-woven particle filter included. The mask is a tight fitting facepiece (usually a full face mask) and generally made from hard plastic materials with soft plastic parts. Strap can be made from an elastic or nylon. Different types of batteries, if relevant.
SCBAs	SCBAs with mask	Valve system, hose and harness	The valve for the cylinder is typically made of brass or stainless steel. The body of the regulator is typically made of brass or aluminium. The diaphragm that controls the flow of air is made of rubber or silicone. The pressure gauge is typically made of a metal casing with a glass or plastic cover. The gauge itself may be made of brass or stainless steel. The spring and other internal components are typically made of metal or	Mask ⁴³ (B3): facepiece, including visor and strap Cylinder with air (B5)	Mask is made of a soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon The cylinder is typically made of lightweight aluminium or composite materials, such as carbon fibre or fibreglass.

⁴² When the battery is single-use it shall be considered as a different component under B4

⁴³ If the mask has the same technical span as the components part of the main RPD system (e.g. battery and fan), then it shall also be considered part of the main RPD system and not as an replaceable element part of module B3



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			plastic. The air supply hose is typically made of a flexible material, such as rubber or PVC. The harness is typically made of a strong, durable material, such as nylon or Kevlar	Charging battery or disposable battery if relevant (B4)	Different types of batteries, if relevant.
	SCBA with hoods	Valve system, hose and harness	The valve for the cylinder is typically made of brass or stainless steel. The body of the regulator is typically made of brass or aluminium. The diaphragm that controls the flow of air is made of rubber or silicone. The pressure gauge is typically made of a metal casing with a glass or plastic cover. The gauge itself may be made of brass or stainless steel. The spring and other internal components are typically made of metal or plastic. The air supply hose is typically made of a flexible material, such as rubber or PVC. The harness is typically made of a strong, durable material, such as nylon or Kevlar	Hood (B3) Cylinder with air (B5) Charging battery or disposable battery if relevant (B4)	Hoods can be made from lightweight coated fabric with transparent visor. Other hoods look like helmets with a visor, made from hard plastic, and foam parts. The cylinder is typically made of lightweight aluminium or composite materials, such as carbon fibre or fibreglass. Different types of batteries, if relevant.
SARs	Fresh Air Hose with mask	Breathing tube with connector and fittings	The breathing tube is typically made from PVC - it is flexible, lightweight, and resistant to chemicals - or thermoplastic polyurethane (TPU) as it is flexible and durable. Fitting and connectors are mostly made of nylon, known for its strength and resistance to abrasion, or acetal which offers good mechanical properties and chemical resistance	Mask ⁴³ (B3): facepiece, including visor and strap Energy consumption fresh air source (B5)	Mask is made of a soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon.
	Fresh Air Hose with hood	Breathing tube with connector and fittings	The breathing tube is typically made from PVC - it is flexible, lightweight, and resistant to chemicals - or thermoplastic polyurethane (TPU) as it is flexible and durable. Fitting and connectors are mostly made of nylon, known for its strength and resistance to abrasion, or acetal which offers good mechanical properties and chemical resistance	Hood (B3) Energy consumption fresh air source (B5)	Hoods can be made from lightweight coated fabric or nonwoven materials with transparent visor. Other hoods look like helmets with a visor, made from hard plastic, and foam parts.
	Constant flow airline breathing apparatus with mask	Valve system, hose and harness or breathing tube with connector and fittings	See above	Cylinder with air or energy consumption compressor (B5)	Mask is made of a soft, flexible material, such as silicone, thermoplastic or rubber including an attached visor made of a rigid material, such as polycarbonate. Strap can be made from an elastic or nylon The cylinder is typically made of lightweight aluminium or composite materials, such as carbon fibre or fibreglass.
	Constant flow airline breathing apparatus with hood	Valve system, hose and harness or breathing tube with connector and fittings	See above	Hood (B3) Cylinder with air or energy consumption compressor (B5)	Hoods can be made from lightweight coated fabric or nonwoven materials with transparent visor. Other hoods look like helmets with a visor, made from hard plastic, and foam parts. The cylinder is typically made of lightweight aluminium or composite materials, such as carbon fibre or fibreglass.

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In the category of escape hoods, there are several different types available, each designed to provide respiratory protection in emergency situations. These are some common types of escape hoods:

- **Smoke/Fire Escape Hoods:** specifically designed to protect against smoke, toxic gases, and particles encountered during fire emergencies. They often feature a built-in filter system to remove harmful substances from the inhaled air.
 - **Hood:** Covers the head and forms a seal around the neck to protect against smoke and toxic gases. Made of heat-resistant, flame-retardant materials such as aramid fibers, Nomex, or other fire-resistant fabrics.
 - **Filter:** Removes harmful particles and gases present in smoke, such as carbon monoxide, hydrogen cyanide, and other toxic substances. Typically consists of activated carbon, impregnated carbon, and other specialized materials to adsorb smoke particles and toxic gases.
 - **Straps:** Secure the hood in place and ensure a snug fit. Usually made of durable synthetic materials like nylon or polypropylene.
- **Chemical Escape Hoods:** designed to provide protection against a wide range of chemical hazards, such as toxic gases, vapours, and aerosols. They typically incorporate specialized filters or cartridges that can adsorb or neutralize the specific chemicals.
 - **Hood:** Covers the head and provides a seal around the neck and face. Constructed from chemical-resistant materials such as neoprene, butyl rubber, or other barrier films that provide protection against a wide range of chemicals.
 - **Chemical Cartridges/Filters:** Contains specific chemical sorbents or neutralizing agents to remove or neutralize hazardous gases, vapors, and aerosols. Composed of various materials depending on the specific chemicals to be removed or neutralized. This may include activated carbon, specific sorbent materials, or combinations of different filtration media.
 - **Straps:** Keep the hood securely attached to the wearer's head. Similar to smoke/fire escape hoods, straps are typically made of durable synthetic materials like nylon or polypropylene.
- **Biological Escape Hoods:** designed to protect against biological hazards, including infectious agents and airborne pathogens. They feature filters that can capture and prevent the passage of microorganisms or particulates associated with biological threats.
 - **Hood:** Covers the head, including the face and neck, and forms a tight seal. Made from materials that provide a barrier against biological agents, such as nonwoven fabrics like polypropylene or polyester that can filter out airborne particles.
 - **Filters:** Designed to capture and prevent the passage of biological agents, such as bacteria, viruses, and other airborne pathogens. Utilize materials like HEPA (High-Efficiency Particulate Air) filters, which are composed of densely packed, fine fibers or membranes to capture microscopic particles.
 - **Straps:** Securely fasten the hood and maintain a proper fit. Similar to other escape hoods, straps are typically made of durable synthetic materials like nylon or polypropylene.
- **Combination Escape Hoods:** designed to provide protection against multiple hazards. They may incorporate a combination of filters, cartridges, or technologies to address various types of contaminants, such as smoke, chemicals, and biological agents.
 - **Hood:** Covers the head and provides a seal around the neck and face. The hood material can vary depending on the specific hazards addressed by the escape hood, and may use a combination of fire-resistant, chemical-resistant, and barrier fabrics.
 - **Combination Filters/Cartridges:** Incorporates a combination of filtration media, such as activated carbon, HEPA (High-Efficiency Particulate Air) filters, and chemical sorbents, to address multiple hazards simultaneously. Incorporate multiple materials based on the targeted contaminants. This can include activated carbon, specific sorbents, and filtration media such as synthetic fibers or membranes.
 - **Straps:** Ensure a secure and comfortable fit of the hood. Typically made of durable synthetic materials like nylon or polypropylene.
- **Oxygen Escape Hoods:** supply of breathable oxygen in oxygen-deficient environments. They typically come with a built-in oxygen cylinder or a connection to an external oxygen source, ensuring the wearer has a safe source of breathable air.
 - **Hood:** Covers the head and forms a seal around the neck and face. Constructed from lightweight, flexible, and airtight materials such as silicone, neoprene, or elastomers that ensure a proper seal and facilitate oxygen flow.

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- Oxygen Supply System: Consists of an integrated oxygen cylinder or a connection to an external oxygen source, providing a source of breathable air. Consists of components made of materials compatible with oxygen, such as brass, stainless steel, or lightweight composite materials.
- Regulator: Controls the flow of oxygen to the wearer. Typically made of metals like brass or aluminum to control the flow of oxygen.
- Straps: Securely fasten the hood and maintain proper positioning. Similar to other escape hoods, straps are usually made of durable synthetic materials like nylon or polypropylene.
- Emergency Escape Hoods: designed for general emergency situations, providing respiratory protection against a range of airborne contaminants, including smoke, toxic gases, and particles.
 - Hood: Covers the head, including the face and neck, and forms a tight seal. The hood material can vary depending on the specific hazards addressed by the escape hood, and may use a combination of fire-resistant, chemical-resistant, and barrier fabrics.
 - Filter/Cartridge: Removes or neutralizes a range of contaminants, such as smoke, chemicals, and biological agents. Combines various filtration materials, including activated carbon, specific sorbents, and synthetic fibers or membranes for effective particle capture.
 - Straps: Securely fasten the hood to ensure a proper fit. Typically made of durable synthetic materials like nylon or polypropylene.

ANNEX B – EXAMPLE OF CONTENT DECLARATION

To differentiate between the main RPD system and, if relevant, the filters, hoods or replaceable masks, single-use batteries and cylinders, the content declaration can be done as presented in Table 8 below. If more relevant for the scope of the EPD, a different table can be reported excluding certain elements or including additional information. The example given is for a full facepiece respirator with combination gas particulate filters. For packaging Table 9 can be used.

Table 8 Example of content declaration with split between different RPD components

RPD COMPONENT	WEIGHT RPD COMPONENT [kg]	MATERIALS IN COMPONENT	WEIGHT OF MATERIAL [kg]	wt% IN RPD COMPONENT	wt% IN COMPLETE RPD	RECYCLED CONTENT
Select out of: Main RPD system, Filter, Hood, Disposable battery, Cylinder, or Other replaceable element	Give for each RPD component its weight for 1 unit	Give per RPD component its individual materials or chemical substances present.	Provide the mass for each material	Provide the mass percentage of the materials per relevant RPD component.	Provide the mass percentage of the materials per complete RPD system.	See section 5.4.4.1
Main RPD system	0.400 kg (80%)	Silicone rubber	0.200 kg	50%	40%	0%
		Polypropylene	0.120 kg	30%	24%	0%
		Polycarbonate	0.050 kg	12.5%	10%	0%
		Nylon	0.030 kg	7.5%	6%	0%
Filters	0.100 kg (20%)	Polypropylene	0.020 kg	20%	4%	0%
		Carbon black	0.070 kg	70%	14%	0%
		Glass fibre	0.010 kg	10%	2%	0%

Table 9 Example of packaging declaration split between different RPD components

RPD COMPONENT	PACKAGING TYPE	PACKAGING MATERIAL	WEIGHT OF MATERIAL [kg]	WT% IN RPD COMPONENT	WT% IN COMPLETE RPD	RECYCLED CONTENT	PACKAGING FUNCTION
Select out of: Main RPD system, Filter, Hood, Disposable battery, or Cylinder	Give per RPD component its individual packaging elements. e.g. bag, box, pallet etc.	Give for each packaging type the material. e.g. low-density polypropylene, cardboard, wood, etc	Provide the mass for each material for 1 unit.	Provide the mass percentage of each material per RPD component.	Provide the mass percentage of each material per complete RPD system.	See section 5.4.4.1	Consumer or distribution packaging. See 5.4.4.2
Main RPD system	Product bag	Polyethylene	0.010 kg	7.5%	7%	Consumer packaging	70%
	Product box	Cardboard	0.010 kg	7.5%	7%	Consumer packaging	50%
	User instructions	Paper	0.020 kg	15%	14%	User instructions	0%
	Shipper box	Cardboard	0.010 kg	7.5%	7%	Distribution packaging	100%
	Pallet	Wood	0.083 kg	62.5%	58%	Distribution packaging	0%
	Total		0.133 kg	100%	93%	N/A	17%
Filters	Product bag	Polyethylene	0.05 kg	50%	3.5%	Consumer packaging	50%
	Product box	Cardboard	0.05 kg	50%	3.5%	Consumer packaging	50%
	Total		0.01 kg	100%	7%	N/A	50%

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ANNEX C – CALCULATION RULES FOR USER SCENARIOS WHEN COMPARING EPDS

The RPD wearer/EPD user may want to compare the product(s) results of one EPD to the product(s) results of another EPD. The modularity approach of this PCR allows for this, as outlined in section 4.3.1. In such cases, to ensure fair comparisons between different RPDs, some rules must be followed:

1. The products must perform the same function and provide the same level of protection.
2. When comparing only single-use RPDs⁴⁴, the impacts associated with the life cycle modules from A1-A5, B1 and C1 can be directly compared because one product represents one use.
3. When comparing only reusable RPDs the following steps should be taken:
 - a. First, rescale the impacts associated with life cycle modules A1-A5, B1 and C1 by dividing these modules by the estimated technical lifespan for each RPD respectively and multiply with the chosen technical lifespan for the comparison. An example is further illustrated for three different product systems in the table below, when choosing system Z's technical lifespan (3000 hours) as reference:

System (declared unit)	Impact	Calculation
System X	3 kg CO ₂ -eq. (A1-A5, B1, C1)	$\frac{3 \text{ kg CO}_2\text{eq}}{1000 \text{ hours}} \times 3000 \text{ hours} = 9 \text{ kg CO}_2\text{eq}$
System Y	4 kg CO ₂ -eq. (A1-A5, B1, C1)	$\frac{4 \text{ kg CO}_2\text{eq}}{2000 \text{ hours}} \times 3000 \text{ hours} = 6 \text{ kg CO}_2\text{eq}$
System Z	2.5 kg CO ₂ -eq. (A1-A5, B1, C1)	$\frac{2.5 \text{ kg CO}_2\text{eq}}{3000 \text{ hours}} \times 3000 \text{ hours} = 2.5 \text{ kg CO}_2\text{eq}$

- b. Then, rescale the impacts associated with life cycle modules B2-B5, and Bx (if relevant) and C2-C5, and Cx (if relevant) by multiplying with the number of replacements of each individual component (respectively filter unit, hood, disposable battery and cylinder) during the chosen technical lifespan for the comparison. An example is further illustrated for three different product systems in the table below, when choosing system Z's estimated technical lifespan (3000 hours) as reference:

System (declared unit)	Impact	Expected replacements	Calculation
System X	1.5 kg CO ₂ -eq. (B2) 0.5 kg CO ₂ -eq. (B3) 0.4 kg CO ₂ -eq. (C2) 0.1 kg CO ₂ -eq. (C3)	50 filters, 10 hoods Lifespan = 1000 hours	<u>Filters (B2 & C2)</u> $1.5 \text{ kg CO}_2\text{eq} \times \left(\frac{50}{1000h} \times 3000h\right) = 225 \text{ kg CO}_2\text{eq}$ $0.4 \text{ kg CO}_2\text{eq} \times \left(\frac{50}{1000h} \times 3000h\right) = 60 \text{ kg CO}_2\text{eq}$ <u>Hoods (B3 & C3)</u> $0.5 \text{ kg CO}_2\text{eq} \times \left(\frac{10}{1000h} \times 3000h\right) = 15 \text{ kg CO}_2\text{eq}$ $0.1 \text{ kg CO}_2\text{eq} \times \left(\frac{10}{1000h} \times 3000h\right) = 3 \text{ kg CO}_2\text{eq}$
System Y	1 kg CO ₂ -eq. (B2) 0.4 kg CO ₂ -eq. (B3)	60 filters, 16 hoods	<u>Filters (B2 & C2)</u>

⁴⁴ In some cases for single-use RPDs the lifespan has an important impact and to have a more representative impact of the user the impact of each module shall be divided by the estimated technical lifespan for each RPD respectively and multiplied with the chosen technical lifespan for the comparison.

	0.5 kg CO ₂ -eq. (C2) 0.1 kg CO ₂ -eq. (C3)	Lifespan = 2000 hours	$1 \text{ kg CO}_2\text{eq} \times \left(\frac{60}{2000h} \times 3000h\right) = 90 \text{ kg CO}_2\text{eq}$ $0.5 \text{ kg CO}_2\text{eq} \times \left(\frac{60}{2000h} \times 3000h\right) = 45 \text{ kg CO}_2\text{eq}$ <u>Hoods (B3 & C3)</u> $0.4 \text{ kg CO}_2\text{eq} \times \left(\frac{16}{2000h} \times 3000h\right) = 9.6 \text{ kg CO}_2\text{eq}$ $0.1 \text{ kg CO}_2\text{eq} \times \left(\frac{16}{2000h} \times 3000h\right) = 2.4 \text{ kg CO}_2\text{eq}$
System Z	0.5 kg CO ₂ -eq. (B2) 0.2 kg CO ₂ -eq. (B3) 0.2 kg CO ₂ -eq. (C2) 0.1 kg CO ₂ -eq. (C3)	80 filters, 20 hoods Reference lifespan = 3000 hours	<u>Filters (B2 & C2)</u> $0.5 \text{ kg CO}_2\text{eq} \times \left(\frac{80}{3000h} \times 3000h\right) = 40 \text{ kg CO}_2\text{eq}$ $0.2 \text{ kg CO}_2\text{eq} \times \left(\frac{80}{3000h} \times 3000h\right) = 16 \text{ kg CO}_2\text{eq}$ <u>Hoods (B3 & C3)</u> $0.2 \text{ kg CO}_2\text{eq} \times \left(\frac{20}{3000h} \times 3000h\right) = 4 \text{ kg CO}_2\text{eq}$ $0.1 \text{ kg CO}_2\text{eq} \times \left(\frac{20}{3000h} \times 3000h\right) = 2 \text{ kg CO}_2\text{eq}$

4. When comparing a single-use RPD with a reusable RPD, the single-use and reusable RPD must perform the same function and the estimated technical lifespan of the reusable RPD must be accounted for. This means that a few steps need to be taken:
 - a. First, the impacts associated with life cycle modules A1-A5, B1 and C1 for the single-use RPD shall be multiplied by the total number of expected uses during the estimated technical lifespan of the reusable RPD. An example is further illustrated comparing two product systems in the table below:

System (declared unit)	Impact	Calculation
System X (reusable)	3 kg CO ₂ -eq. (A1-A5, B1, C1)	310 expected uses (lifespan of approx. 2500 hours)
System Y (single use)	0.2 kg CO ₂ -eq. (A1-A5, B1, C1)	$0.2 \text{ kg CO}_2\text{eq} \times 310 = 62 \text{ kg CO}_2\text{e}$

- b. Then, rescale the impacts associated with life cycle modules B2-B4, and Bx (if relevant) and C2-C5, and Cx (if relevant) of the reusable RPDs by multiplying with the number of replacements of each individual component (respectively filter unit, hood, disposable battery and cylinder) during the chosen technical lifespan for the comparison. See the example in point 3 (b) above.

RESPIRATORY PROTECTIVE DEVICES
PRODUCT CATEGORY CLASSIFICATION: MULTIPLE UN CPC

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