DISPOSABLE SURGICAL DRAPES, GOWNS, AIR SUITS AND FACE MASKS

PRODUCT CATEGORY CLASSIFICATION: UN CPC 35290

PCR 2017:01
VERSION 2.0.0

VALID UNTIL 2028-02-28

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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 declarations[1] 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.

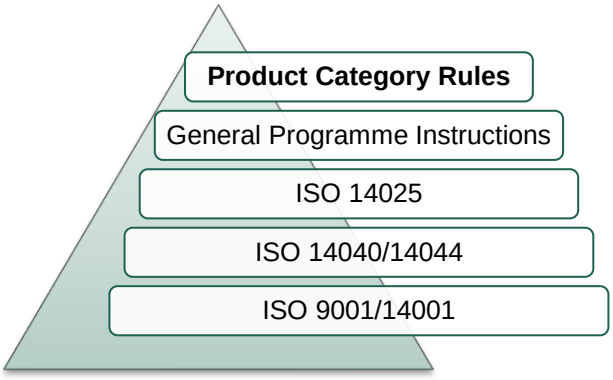

Figure 1 The hierarchy between PCRs, standards and other documents. EN 15804 and ISO 21930 are normative standards for construction products only.

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.

2 GENERAL INFORMATION

2.1 ADMINISTRATIVE INFORMATION

Name:	Disposable surgical drapes, gowns, air suits and face masks
Registration number and version:	2017:01, version 2.0.0
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 Moderator:	Dr. Paolo Simon Ostan, Freelance Consultant, paolo.simon@mail.com
PCR Committee:	Paul Hartmann AG, 3M, Dr. Paolo Simon Ostan
Date of publication and last revision:	2024-02-28 (version 2.0.0) See Section 8 for a version history of the PCR.
Valid until:	2028-02-28
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, provided 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 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 SCOPE OF PCR

2.2.1 PRODUCT CATEGORY DEFINITION AND DESCRIPTION

This document provides Product Category Rules (PCR) for the assessment of the environmental performance of disposable surgical drapes, gowns, air suits and face masks used for patients, clinical staff and equipment, and the declaration of this performance by an EPD. The product category corresponds to a subset of UN CPC 35290 Other articles for medical or surgical purposes.

In particular the UN CPC's classification hierarchy is:

Group	Class	Subclass	Description
352			Pharmaceutical products
	3529	35290	Other articles for medical or surgical purposes

For additional information about the classification, see *https://unstats.un.org/unsd/classifications/Family/Detail/1074*.

The products included in the scope of this PCR document are the following disposable (single use) articles:

- **surgical drapes:** drapes covering the patient or equipment to prevent transfer of infective agents
- **surgical gowns:** gowns worn by member of a surgical team to prevent transfer of infective agent
- **clean air suits:** suits intended and shown to minimize contamination of the operating wound by the wearer's skin scales carrying infective agents via the operating room air thereby reducing the risk of wound infection
- **face masks:** masks worn by member of a surgical team to prevent transfer of infective agent

The PCR includes both sterile and non-sterile products.

Surgical drapes, gowns, clean air suits and face masks may be packed individually or may be part of a surgical procedure pack.

Surgical procedure packs are also included in the scope of the PCR. A procedure pack comprises of a series of disposable drapes, gowns and other accessories that are packaged together and placed on the market with the purpose of being used for medical treatments or surgical procedures. All the accessories included in the procedure packs that are not directly assembled with the drapes and gowns, and are not classified as drapes and gowns, clean air suits or face masks (e.g. hand towels, additional adhesive tapes, fluid collection pouches, tubes, etc.) shall be excluded from the LCA.

The manufacturer of a procedure pack may manufacture all of the components or source them from different manufacturers.

Disposable drapes, gowns, air suits and face masks are usually made by nonwoven fabrics and/or laminated films; the main materials used are plastics (e.g. PP, PE, PU, …) or organic man-made fibres such as viscose. The PCR covers these products regardless of the materials used to produce them.

The following products are excluded from the purpose of this PCR document:

- disposable surgical caps
- nonwoven wipes and hand towels
- reusable drapes, gowns, clean air suits and face masks

2.2.2 GEOGRAPHICAL SCOPE

This PCR may be used globally.

2.2.3 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 2.0.0

This PCR is available for open consultation from 2022-04-13 until 2022-06-12, during which any stakeholder is 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.

- Nikolaos T. Athanassoulis, Mega Disposables S.A.

3.1.2 VERSION 1.0

This PCR was available for open consultation from 2016-10-18 until 2016-12-18, during which any stakeholder was able to provide comments by contacting the PCR Moderator and/or the Secretariat.

A total of 218 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.

3.2 PCR REVIEW

3.2.1 VERSION 2.0.0

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:	Bárbara M. Civit
Review dates:	2023-03-09 until 2023-05-30

3.2.2 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:	Hüdai Kara
Review dates:	2017-01-23 until 2017-04-07

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:

- International EPD System. www.environdec.com.
- GlobalEPD
- EPD Norway
- IBU
- PEP ecopassport®
- EarthSure
- EDF
- KEITI Environmental Declaration of Products
- JEMAI EcoLeaf
- JEMAI CFP Program
- UL Environment
- ASTM International EPD Program
- NSF International National Center for Sustainability Standards EPD
- SM Transparency Report Program
- FPInnovations EPD Program on wood building products
- ICC Evaluation Service Environmental Product Declaration Program
- Carbon Leadership Forum PCRs
- BRE Global EN EPD Verification Scheme
- DAPcons®
- SCS Global Services

No existing PCRs or other relevant 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 (declared unit, system boundary, allocation methods, impact categories, data quality rules, etc.) were primarily based on the following underlying studies:

- LCA of Mayo stand – Hartmann Foromed, 2016-2020
- Internal studies on surgical drapes – 3M 2016

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 2.2.1.

4.1 DECLARED UNIT

The products included in the scope of this PCR are disposable (single use) articles used as medical devices for members of a surgical team, patients and equipment to prevent transfer of infective agents, as defined in Section 2.2.1.

The declared unit is 1 (one) product unit including packaging, in particular:

- 1 drape,
- 1 gown,
- 1 clean air suits,
- 1 face mask, or
- 1 surgical procedure pack.

Distribution and consumer packaging shall be considered in the LCA including the intermediate packaging of any component in the case of surgical procedure packs.

EPDs based on this PCR but for different product types (drapes, gowns, etc.) are not comparable since the declared unit change depending on the product type. To make a relevant comparison within the same product type, other features shall also be taken into consideration, such as weight, dimensions and the intended use of the products.

The declared unit shall be stated in the EPD. The environmental impact shall be given per declared unit. EPD

4.2 TECHNICAL SPECIFICATION

The following information on the product shall be included in the EPD, if applicable. Any exclusion shall be justified. The use of alternative standards shall be justified.

- Description of the intended use of the product including the surgery procedure type
- Type of sterilization
- Type of packaging
- Compliance with the EN 13795, by meeting the performance requirements depending on the intended use of product(s) and/or specific components of the product(s)
- The level of liquid barrier performance of the product(s) and/or specific accessories, according to ANSI/AAMI PB70:2012

A technical description of the product in terms of functional characteristics (see the following tables), main product components and/or materials shall also be reported in the EPD.

Table 1 General information.

Product	Information	Test method
Surgical drapes	Size (cm)	
	Weight (g)	
	Fire reaction class	CFR 1610
Surgical gowns and clean air suits	Size (M, L, XL, etc.)	
	Weight (g)	
	Fire reaction class	CFR 1610
Face masks	Size (cm)	

	Weight (g)	
	Fire reaction class	CFR 1610
Surgical procedure packs	For each article (drape, gown, etc.) included in the pack the above information shall be reported	

Table 2 Technical characteristics[2].

Drapes, gowns, air suits		
Characteristic	**Test method**	**Unit**
Resistance to microbial penetration - dry	ISO 22612	CFU
Resistance to microbial penetration - wet	ISO 22610	I_B
Cleanliness - microbial	ISO 11737-1	CFU/100 cm^2
Cleanliness - particulate matter	ISO 9073-10	IPM
Linting	ISO 9073-10	log_{10}
Resistance to liquid penetration	EN 20811	cm (H_2O)
Bursting strength - dry	ISO 13938-1	kPa
Bursting strength - wet	ISO 13938-1	kPa
Tensile strength dry	EN 29073-3	N
Tensile strength wet	EN 29073-3	N
Face masks		
Characteristic	**Test method**	**Unit**
Bacterial filtration Efficiency (BFE)	EN 14683	%
Total bioburden	EN 14683 / ISO 11737-1	cfu/g
Splash resistance pressure	EN 14683	kPa
Differential pressure (DP)	EN 14683	Pa/cm^2

Other specifications are voluntary.

NOTE 1: The information shall be coherent with the corresponding Technical Data Sheet.

NOTE 2: Equivalent standard methods, other than those indicated, may be used. The latest version of the standards should be used.

NOTE 3: Some technical characteristics are not applicable to clean air suits (e.g. Resistance to microbial penetration – wet, Resistance to liquid penetration, etc.)

Lifespan and reference service life (RSL) are not applicable for this product category.

4.3 SYSTEM BOUNDARY

The scope of this PCR and EPDs based on it is cradle-to-grave.

4.3.1 LIFE-CYCLE STAGES

For the purpose of different data quality rules and for the presentation of results, the life cycle of the product is divided into three life cycle stages:

- Upstream processes (from cradle-to-gate)

[2] Adapted from EN 13795:2011+A1:2013

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

In the 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.

4.3.1.1. Upstream processes

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

- extraction and processing of raw materials,
- recycling processes of secondary materials from other product life cycles,
- production of input components (e.g. polymers, man-made fibres, etc.),
- production of semi-products used in the core process (e.g. films, nonwovens, laminates, adhesives, etc.),
- production of the accessories that are directly assembled with the drapes and gowns (e.g. double coated tape, velcro, pouches, tube and cord organizers, hook, loop and tie strings, etc.),
- production of auxiliary products used such as detergents for cleaning, etc.,
- 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),
- generation of electricity and production of fuels, steam and other energy carriers used in upstream processes,
- production of distribution and consumer packaging.

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.

For modelling of infrastructure and capital goods, see Section 4.3.2.

4.3.1.2. Core processes

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

- transportation of materials and other input components to the manufacturing of the product under study,
- manufacturing and assembly of the product under study,
- sterilization of the product, if applicable,
- storage,
- maintenance of manufacturing equipment, if they make up a significant share of the overall attributable environmental impact,
- end-of-life treatment of manufacturing waste, 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. Manufacturing of a minimum of 99% of the total weight of the declared product including packaging shall be included.

The following processes shall not be included:

- manufacturing of all the accessories of surgical procedure packs that are not directly assembled with the drapes and gowns and are not classified as drapes and gowns, clean air suits or face masks (e.g. hand towels, additional adhesive tapes, fluid collection pouches, tubes, etc.)
- business travel of personnel,
- travel to and from work by personnel, and
- research and development activities.

For modelling of infrastructure and capital goods, see Section 4.3.2.

4.3.1.3. Downstream processes

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

- transportation of the product to retailer/consumer,
- end-of-life treatment of the used product and its packaging, including transportation, and
- generation of electricity and production of fuels, steam and other energy carriers used in downstream processes.

For modelling of infrastructure and capital goods, see Section 4.3.2.

4.3.2 INFRASTRUCTURE AND CAPITAL GOODS

In general, the production and end-of-life processes of infrastructure or capital goods[3] 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 (land use and toxicity indicators shall only be mentioned if declared in the EPD):

The results of the impact categories abiotic depletion of minerals and metals, land use, human toxicity (cancer), human toxicity, non-cancer and ecotoxicity (freshwater) 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 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 leaves nature and enters 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. If there is an inflow of recycled material to the product system in the production/manufacturing stage, the transport from the scrapyard/collection site to the recycling plant, the recycling process, and the transportation from the recycling plant to the site where the material is being used shall be included. If there is an outflow of material or component to recycling, the transportation of the material to the scrapyard/collection site shall be included. The material or component going to recycling is then an outflow from the product system.

See Section 4.6 for further guidance.

[3] 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.

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

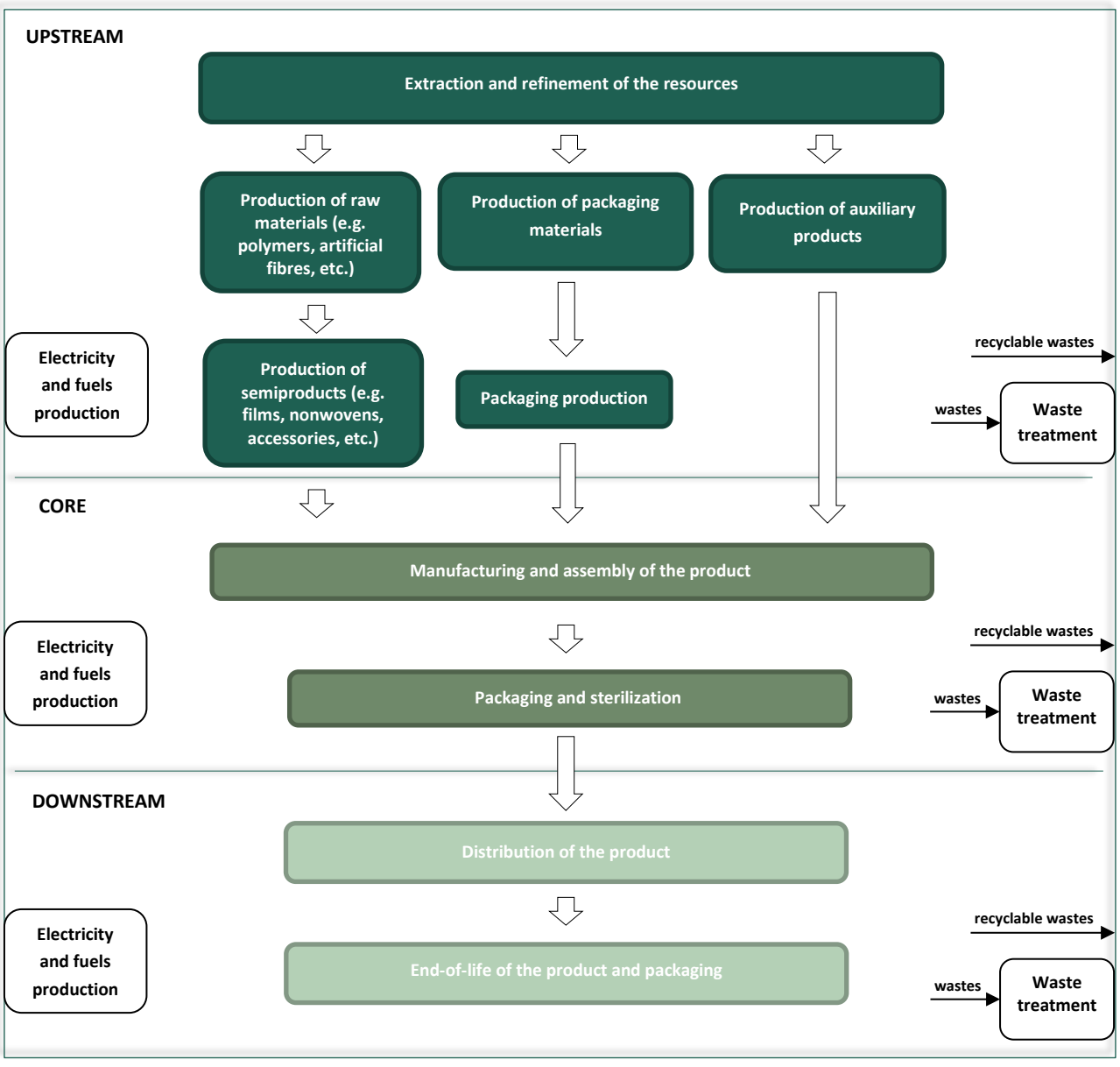

Figure 2 System diagram illustrating the processes that shall be included in the product system, divided into upstream, core and downstream processes. The illustration of processes to include may not be exhaustive.

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. Further, the cut-off shall be possible to verify 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.

For key processes in the product system, Table 3 provides specific allocation guidance.

PROCESS	MAIN PRODUCT AND CO-PRODUCTS	ALLOCATION METHOD
Product assembly[4]	Disposable surgical product 1 Disposable surgical product 2 . . Disposable surgical product "*n*"	Inputs shall be allocated between the products 1 to *n* in proportion to their economic value. If economic allocation has been used, a specific sensitivity analysis shall be provided to the verifier and the monitoring of the relationship between results and current economic value shall be documented and updated. The economic allocation shall be justified and described in the LCA report and declared in the EPD.

Table 3 Allocation method for key processes in the product system.

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):

[4] Assembly of the product (core process) is usually carried out in multiproduct plants where could be difficult to establish a physical relationship since a wide range of different products are made with various process phases.

- 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 ware 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".

Specific data shall be used for the core processes. Specific data shall be used for upstream and downstream processes, when available, otherwise generic data may be used. Generic data should be used in cases in which they are representative for the purpose of the EPD, e.g. for bulk and raw materials on a spot market, if there is a lack of specific data on the final product or if a product consists of many components.

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 (e.g., not be based on marginal data and not 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) shall be met on the level of the product system,
- datasets shall represent average values for a specific reference year; however, how data are generated could vary, e.g. over time, and then they should have the form of a representative annual average value for a specified reference period (such deviations shall be justified and declared in the EPD), and
- the representativeness of the data shall be assessed to be better than ±5%, in terms of the environmental impact calculated on the basis of the data, of data that is fully representative for the given temporal, technological and geographical context.

If selected generic data that meets the above data quality 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 may include a data quality declaration to demonstrate the share of specific data, selected generic data and proxy data contributing to the results of the environmental impact indicators.

4.7.2 EXAMPLES OF DATABASES FOR GENERIC DATA

No specific databases are recommended for generic data.

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

Below are further data quality requirement per life-cycle stage. 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 and activities upstream in a supply chain over which the EPD owner direct management control shall be specific and collected on site.
- Data referring to contractors that supply main semiproducts, packaging, or main auxiliaries should be requested from the contractor as specific data, as well as infrastructure, where relevant. In particular, specific data should be collected for amounts of inputs and outputs of the following manufacturing processes[5]:
  - Nonwovens,
  - films and laminates, and
  - adhesives used to join layers.

  In case specific data are lacking, selected generic data may be used. If this is also lacking, proxy data may be used. If selected generic data or proxy data are used it shall be clearly justified in the EPD.
- 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.
- 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 market[6].
  4. Electricity consumption mix on the market[7].

  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. If the composition of the residual grid mix on the market has not been publicly disclosed, it may conservatively be estimated by subtracting renewables from the consumption mix on the market.

  "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.

[5] List shall be considered as non-exhaustive.

[6] 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.

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

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

- Packaging: specific data shall be used for the consumer packaging production if it is under the direct control of the organization or if the environmental impact related to the consumer packaging production is more than 10% of the total product environmental indicators. In other cases, generic data may be used. When consumer packaging shows the organization's logo, the LCA report should report 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.
- Goods: 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.
- If several plants are involved in the production process, an average virtual plant shall be defined by accounting for the annual production (expressed in mass) as the weighting factor.
- Services: Specific data shall be used for the consumption of materials, chemicals, steam, heat, electricity, etc., necessary for execution of the service
- 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 market[8].
    4. Electricity consumption mix on the market[9]. This option shall not be used for electricity used in processes over which the manufacturer (EPD owner) has direct control.

  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. If the composition of the residual grid mix on the market has not been publicly disclosed, it may conservatively be estimated by subtracting renewables from the consumption mix on the market.

  "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.

4.7.3.3. Downstream processes

- Data for the use stage are usually based on scenarios, but specific data should be used when available and relevant.
- Data on the emissions from the use stage should be based on documented tests, verified studies in conjunction with average or typical product use, or recommendations concerning suitable product use. Whenever applicable, test methods shall be internationally recognised.
- The use of electricity 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:

[8] 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.

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

1. Residual electricity mix on the market.
2. Electricity consumption mix on the market.

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. If the composition of the residual grid mix on the market has not been publicly disclosed, it may conservatively be estimated by subtracting renewables from the consumption mix on the market.

"The market" in the above hierarchy may correspond a national electricity market, if this can be justified.

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 specific a 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. Calculated as a fixed long transport of 1 000 km transport by lorry.

- Scenarios for the end-of-life stage shall be based on available municipal solid waste statistics from the region/geographical area. Waste management of packaging shall be included in the downstream module, based on scenarios for the relevant market. If various regions/geographical areas are considered in the EPD, the results of waste management shall be based on a representative scenario, e.g. as an average defined by amount of products distributed in the areas as the weighting factor. The potential environmental impact of waste management of the product and its packaging shall be reported separately from other results. Scenarios for 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 and in the EPD.
- The calculation of the environmental impacts due to the end-of-life stage of the products and their packaging shall be based on allocation rules in Section 4.6.2. Among others, this means that:
  - Impacts of landfilling shall be attributed 100% to the product.
  - In case of recycling or other recovery (e.g. composting) impacts shall be borne by the product until it enters the facility gate where the process takes place in accordance with the Polluter Pays Principle. Benefits and credits of recovery are outside the system boundaries. An estimation of the avoided impacts due to such recovery could be declared separately as additional environmental information (see Section 5.4.6).

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. Alternative regional 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 difference between the different sets of indicators, as they may appear to the reader to display duplicate information.

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

Apart from the required inventory 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 PRODUCTS FROM THE SAME COMPANY

Several sets of results, reflecting different products, are not allowed to be declared in the same EPD. However, similar products from a single or several manufacturing sites covered by the same PCR and manufactured by the same company with the same major steps in the core processes may be grouped and thereby included in the same EPD. 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 – a representative product. The choice of the representative product shall be justified in the EPD, using, where applicable, statistical parameters. For example, the choice may be based on production volumes. In this option, the content of the representative product shall be declared in the content declaration.
- For each indicator, declare the highest result of the included products (i.e., the results of a “worst-case product”, which may be the results of 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.

The first two options are only possible if none of the declared environmental impact indicator results differ by more than 10% between any of the included products. The third option is possible also if variations are larger than 10%.

The option chosen shall be clearly described in the EPD.

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 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.

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 products[10].

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 (m^3)
  - 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 CO_2 equivalents.
- Three significant figures[11] 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.

[10] Therefore, results of normalization are not allowed to be reported in the EPD.

[11] 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 $1.2*10^2$ 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.[12]
  - 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 □)
- Environmental performance (see Section 5.4.5)
- Additional environmental information (see Section 5.4.6)
- Additional social and economic information (see Section 5.4.7)
- References (see Section 5.4.9)

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 operator[13]
- Date of publication (issue): 20XX-YY-ZZ

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

[13] 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.

- 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.

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 verification[14] 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: PCR 2017:01 Disposable surgical drapes, gowns air suits and face masks used for patients, clinical staff and equipment, Version 2.0.0, UN CPC 35290.
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
Independent third-party verification of the declaration and data, according to ISO 14025:2006, via: ☐ EPD verification by individual verifier Third-party verifier: *<name, organisation, and signature of the third-party verifier>*

[14] 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.

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: *<name, organisation>* is an approved certification body accountable for the third-party verification The certification body is accredited by: *<name of accreditation body & accreditation number, where applicable>*
OR
Independent third-party verification of the declaration and data, according to ISO 14025:2006 via: ☐ EPD verification by EPD Process Certification* Internal auditor: *<name, organisation>* Third-party verification: *<name, organisation>* is an approved certification body accountable for third-party verification Third-party verifier is accredited by: *<name of accreditation body & accreditation number, where applicable>* *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[15] of the EPDs, see GPI v4, Section 7.5.
Procedure for follow-up of data during EPD validity involves third-party verifier: ☐ Yes ☐ No

5.4.3 PRODUCT INFORMATION

The product information section of the EPD shall include:

- address and contact information to 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,
- 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. Other relevant codes for product classification may also be included, e.g.
  - Common Procurement Vocabulary (CPV),

[15] 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.

  - 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 of the product, including its application/intended use and the surgery procedure type,
- 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,
- technical description of the product in terms of functional characteristics, main product components and or materials, etc. in accordance to section 4.2
- 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,
- the type of EPD system boundary: "cradle-to-grave",
- information on which life-cycle stages are not considered (if any), with a justification of the omission,
- key assumptions regarding the end-of-life stage scenario, 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,
- any additional information about the underlying LCA-based information, such as cut-off rules, data quality, allocation methods, and other methodological choices and assumptions,
- a description of the material properties of the product with a declaration of relevant physical or chemical product properties, such as density, etc., and
- if end-of-life treatment is not included, the EPD shall contain a statement that it shall not be used for communicating environmental information to consumers/end users of the product.

5.4.4 CONTENT DECLARATION

The content declaration section shall declare the weight of one unit of product, as purchased, and 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 shall also declare the energy content of product in MJ. Its estimation shall be made considering the gross calorific value of the product. Only the energy that is suitable for an eventual energy recovery at the end-of-life shall be considered (energy content of steel due to its carbon content for example shall not be considered since it is not practically recoverable); the energy content of some products (such paper or plastic based products) is useful information for the end-of-life management.

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),[16] 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 provenience 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.

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 content, 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 of the packaging per product, and the 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 by recycled materials.

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 methods[17] 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.

[16] The GHS document is available at www.unece.org.

[17] 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.

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.

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 difference between the different 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 www.environdec.com/indicators per declared unit, per life-cycle stage and in aggregated form.

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 www.environdec.com/indicators per declared unit, per life-cycle stage and in aggregated form.

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.

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

ANZSIC	Australian and New Zealand Standard Industrial Classification
CPC	Central product classification
CPV	Common procurement vocabulary
EPD	Environmental product declaration
GPI	General Programme Instructions
GTIN	Global trade item number
ISO	International Organization for Standardization
LCA	Life cycle assessment
LCI	Life cycle inventory
NACE/CPA	Classification of products by activity
ND	Not declared
PCR	Product category rules
REACH	Restriction of chemicals
RSL	Reference service life
SI	The International System of Units
UN	United Nations
UNSPSC	United Nations standard products and services code

7 REFERENCES

CEN (2021): EN 15804:2012+A2:2019/AC:2021, Sustainability of construction works – Environmental product declarations – Core rules for the product category of construction products.

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 (2013) ISO/TS 14067:2013, Greenhouse gases – Carbon footprint of products – Requirements and guidelines for quantification and communication.

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

AAMI (2012), ANSI/AAMI PB70/Ed.2, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

Simon Ostan P. (2020) Life Cycle Assessment (LCA) of Mayo stand – Hartmann Foromed, ref. 21315707

8 VERSION HISTORY OF PCR

VERSION 1.0, 2017-04-12

Original version.

VERSION 1.1, 2019-02-13

Updated in accordance with GPI 3.0 and new PCR basic module.

VERSION 1.11, 2019-03-05

Corrected spelling errors and minor editorial changes.

VERSION 1.12, 2019-09-06

- Clarified terms of use.
- Editorial changes.

VERSION 2.0.0, 2024-02-28

- Updated in accordance with GPI 4.0 and new PCR template.
- Editorial changes.

DISPOSABLE SURGICAL DRAPES, GOWNS, AIR SUITS AND FACE MASKS
PRODUCT CATEGORY CLASSIFICATION: UN CPC 35290