

SERVICE OF PROVIDING WASHED AND STERILIZED REUSABLE SURGICAL
DRAPES AND GOWNS USED FOR PATIENTS AND CLINICAL STAFF
PRODUCT CATEGORY CLASSIFICATION: UN CPC 97130

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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. Environmental Product Declarations (EPD) are voluntary documents for a company or organisation to present transparent information about the life cycle environmental impact for their goods or services.

The rules for the overall administration and operation of the programme are the General Programme Instructions, publicly available at www.environdec.com. A PCR complements the General Programme Instructions and the 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.

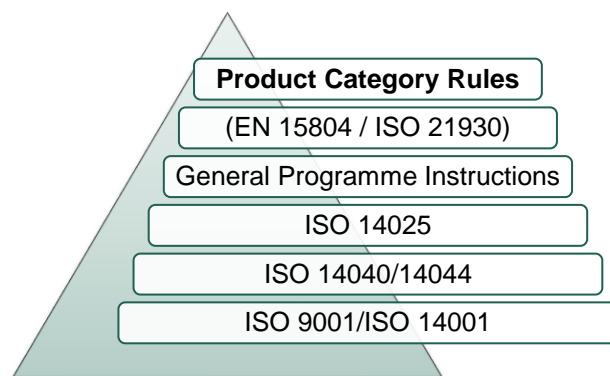


Figure 1 Illustration PCR in relation to the hierarchy of standards and other documents.

Within the present PCR, the following terminology is adopted:

- The term “shall” is used to indicate what is obligatory.
- The term “should” is used to indicate a recommendation, rather than a requirement.
- The term “may” or “can” is used to indicate an option that is permissible

For the definition of 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 via www.environdec.com. Stakeholder feedback on PCRs is very much encouraged. Any comments on this PCR document may be given via the PCR Forum at www.environdec.com or sent directly to the PCR moderator during its development or during the period of validity.

Any references to this document should 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 when necessary, and 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 EPD, Environmental Product Declarations.

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2 GENERAL INFORMATION

2.1 ADMINISTRATIVE INFORMATION

Name:	Service of providing washed and sterilized reusable surgical drapes and gowns used for patients and clinical staff
Registration number and version:	2018:05, version 1.02
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:	Rosangela Spinelli - Lucrezia Volpi LCA Working Group, Science and Methods of Engineering Department (DISMI) – University of Modena and Reggio Emilia – rosangela.spinelli@unimore.it
PCR Committee:	LCA Working Group, Science and Methods of Engineering Department (DISMI) – University of Modena and Reggio Emilia – Rosangela Spinelli - Lucrezia Volpi Servizi Italia S.p.A. Ing. Alessia Magni
Date of publication and last revision:	2020-03-04 (version 1.02)
Valid until:	2022-08-15
Schedule for renewal:	<p>A PCR is valid for a pre-determined period of time 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 document and renewing its validity.</p> <p>A PCR document may be revised during its period of validity provided significant and well-justified proposals for changes or amendments are presented. See www.environdec.com for up-to-date information and the latest version.</p>
Standards conformance:	<ul style="list-style-type: none">General Programme Instructions of the International EPD® System, version 3.0, based on ISO 14025 and ISO 14040/14044PCR Basic Module, CPC Division 97:Other services, version 1.0, dated 2018-XX-YY
PCR language(s):	This PCR was developed and is available in English. In case of translated versions the English version takes precedence in case of any discrepancies.

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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 the washing and sterilization process of reusable surgical drapes and gowns used for patients and clinical staff corresponding to UN CPC 97130 Other textile cleaning services and the declaration of this performance by an EPD®.

In particular the UN-CPC's classification hierarchy is:

Group	Class	Subclass	Description
971			Washing, cleaning and dyeing services
	9713	97130	Other textile cleaning services

For additional information about the classification, see <http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=25>

The services included in the scope of this PCR document are the following:

- The washing and sterilization of surgical reusable drapes: drapes covering the patient or equipment to prevent transfer of infective agents;
- The washing and sterilization of surgical reusable gowns: gowns worn by member of a surgical team to prevent transfer of infective agent;
- The supply and transport of sterilized drapes and gowns from the facility service to the hospitals
- The transport of used drapes and gowns from the hospitals to the facility service.

This PCR applies if the company provides all these services.

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

- The washing and sterilization of reusable surgical masks and capes

This document provides Product Category Rules (PCR) for the assessment of the environmental performance of Washing and sterilization of reusable surgical drapes and gowns used for patients and clinical staff and the declaration of this performance by an EPD. The product category corresponds to UN CPC 97130 Other textile cleaning services.

2.2.2 GEOGRAPHICAL REGION

This PCR is applicable to be used globally.

2.2.3 EPD VALIDITY

An EPD based on this PCR shall be valid from its registration and publication at www.environdec.com and for a five 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 indicators listed in Section 5.4.5.1,
- errors in the declared information, or
- significant changes to the declared product information, content declaration, or additional environmental information.

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

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3 PCR REVIEW AND BACKGROUND INFORMATION

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

3.1 PCR REVIEW

3.1.1 VERSION 1.0

PCR review panel:	The Technical Committee of the International EPD® System. A full list of members available on 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 moderator or PCR committee, and were excused from the review.
Chair of the PCR review:	Lars-Gunnar Lindfors
Review dates:	2018-05-03 until 2018-06-15

3.2 OPEN CONSULTATION

3.2.1 VERSION 1.0

This PCR was available for open consultation from 2017-11-06 until 2018-01-01, during which any stakeholder was able to provide comments by posting on the PCR forum on www.environdec.com or by contacting the PCR moderator.

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.

3.3 EXISTING PCRS FOR THE PRODUCT CATEGORY

No relevant PCRs exist in the International EPD System www.environdec.com, or in other Environmental Product Declarations. The availability of already existing PCRs was checked in the following programmes:

- EarthSure
- EPD Norway
- KEITI Environmental Declaration of Product
- JEMAI EcoLeaf
- JEMAI CFP Program
- Product Environmental Footprint (PEF) pilot phase.

3.4 REASONING FOR DEVELOPMENT OF PCR

This PCR was developed in order to enable publication of Environmental Product Declarations (EPD) for this product category based on ISO 14025, ISO 14040/14044 and other relevant standards to be used in different applications and target audiences.

3.5 UNDERLYING STUDIES

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

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- existing PCR for the professional cleaning services for buildings and passenger train,
- internal LCA studies on surgical drapes and gowns (Servizi Italia S.p.A),
- ETSA Brochure. "Reusable surgical gowns. Options for reduced impact on the environment. Life Cycle Assessment Study Summary". European Textile Services Association ETSA,
- Mikusinska M., 2012. "Comparative Life Cycle Assessment of Surgical Scrub Suits. The Case of Reusable and Disposable Scrubs used in Swedish Healthcare". KTH, Royal Institute of Technology,
- Overcash M., 2012. "A Comparison of Reusable and Disposable Perioperative Textiles: Sustainability State-of-the-Art 2012". International Anesthesia Research Society (May 2012, volume 114, number 5),
- Van den Berghe AJ (Minnesota Technical Assistance Program, University of Minnesota), Zimmer C. (BSMT PSC Healthcare Services, Houston) "Life Cycle Assessments of single-versus multiple-use surgical gown".

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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 FUNCTIONAL UNIT/DECLARED UNIT

The functional unit is service of washing and sterilization of 1 kg of mixed reusable textile gowns or drapes provided in a clean and sterilized form (meeting the quality criteria to be used in an operating room) to the hospital, during one service year. During this time, each drape or gown is used and sterilized for "n" times on average. The service life for all drapes and gowns is calculated basing on "N" times of sterilization. The mix of type and material of the gowns and drapes should be declared in the EPD.

The calculation procedure for defining "1 kg" is the following:

- calculation of the total mass related to each fabric that composes all the drapes and gowns treated during the year;
- calculation of the percentage of the masses of such fabrics, performed on the total one of the treated drapes and gowns;
- transfer of such percentages to 1kg of treated drapes and gowns.

The service can be relative to one or more establishments of the same company. If it is considered more than one establishment, the contribution of each of them is calculated using the criterion of weighed average of the fabric mass treated in that establishment and the total one of the fabric mass of drapes and gowns (in all establishments).

4.2 REFERENCE SERVICE LIFE (RSL)

The service life for all drapes and gowns is calculated based on "N" times of sterilization.

4.3 SYSTEM BOUNDARY

The International EPD® System uses an approach where all attributional processes from "cradle to grave" should be included using the principle of "limited loss of information at the final service". This is especially important in the case of business-to-consumer communication.

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 service is divided into three different life cycle stages:

- Upstream processes (from cradle-to-gate);
- 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. 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 attributional processes are part of the product system and classified as upstream processes:

- Extraction of raw materials (e.g. polymers, textile fibres) for textile layer manufacturing (e.g. microfiber, jersey, polytetrafluoroethylene, polyester)

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- Transport of raw materials (e.g. polymers, textile fibres) for textile layer manufacturing (e.g. microfiber, jersey, polytetrafluoroethylene, polyester)
- Textile layer manufacturing (e.g. microfiber, jersey, polytetrafluoroethylene, polyester) for drapes and gowns manufacturing.
- Transport of textile layer (e.g. microfiber, jersey, polytetrafluoroethylene, polyester) for drapes and gowns manufacturing.
- Drapes and gowns manufacturing.
- Extraction and transport of raw materials for primary and secondary packaging of the new drapes and gowns.
- Manufacturing of primary and secondary packaging of the new drapes and gowns.
- Manufacturing of packaging of chemicals, machineries and equipment to the facility.
- Extraction and production of raw materials (e.g. steel, plastics, etc.) for the production of the machineries and equipment (e.g. washing machine, rolls, closets, etc.) used in the washing and sterilization service.
- Extraction and production of raw materials used in the production of consumables, such as chemicals (e.g. detergents for cleaning, etc.) used in the washing and sterilization service .
- Manufacturing of packaging of drapes and gowns, chemicals, machineries and equipment to the facility.
- Transport of the new machineries and equipment (e.g. washing machine, rolls, closets, etc.) to the facility.
- Transport of chemicals (e.g. detergents for cleaning, etc.) to the facility.
- Transport of drapes and gowns to the facility.
- Transport of the packagings to the facility.

The upstream process is related to 1kg of drapes and gowns allocated considering the number of sterilization cycles in one year in respect of the "N" sterilized cycles in the service life.

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 1% cut-off rule.

4.3.1.2. Core processes

The following attributional processes are part of the product system and classified as core processes:

- Water consumption
- Washing and sterilization of surgical drapes and gowns
- Quality control of surgical drapes and gowns
- Possible reparation of surgical drapes and gowns
- Packaging of sterilized and dirty surgical drapes and gowns
- Transport of sterilized drapes, gowns, closets from the facility service to the hospital
- Transport of dirty drapes, gowns, sacks, rolls from the hospitals to the service facility
- Decontamination of means of transport (trucks), rolls and closets
- Ordinary maintenance of machineries and equipment ²
- Land use of building of service facility.

Processes not listed may also be included. However, the production of the raw materials used for production of all product parts shall be included. A minimum of 99% of the total weight of the declared product including packaging shall be included.

The technical system shall not include:

- Business travel of personnel

² Maintenance activities more frequent than every three years.

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- Travel to and from work by personnel
- Research and development activities

The core process is related to 1kg of drapes and gowns allocated considering the number of sterilization cycles in one year.

4.3.1.3. Downstream processes

The following attributional processes are part of the product system and classified as downstream processes:

- End-of-life processes of the drapes and gowns.
- End-of-life processes of machineries and equipment.
- Treatment of waste generated during reprocessing (e.g. detergents and washing water).
- End-of-life processes of packaging of drapes and gowns (new, dirty and sterilized), of chemicals, of machineries and equipment, of spare parts.

The downstream process is related to 1kg of drapes and gowns allocated considering the number of sterilization cycles in one year in respect of the "N" sterilized cycles in the service life.

4.3.2 OTHER BOUNDARY SETTING

4.3.2.1. Boundary towards nature

Boundaries to nature are defined as flows of material and energy resources from nature into the system. Emissions to air, water and soil cross the system boundary when they are emitted from or leaving the product system.

4.3.2.2. Boundaries in the life cycle

See Section 4.3.1. The EPD may present the information divided into additional sub-divisions.

4.3.2.3. Boundaries towards other technical systems

See Section 4.6.2.

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4.4 SYSTEM BOUNDARY

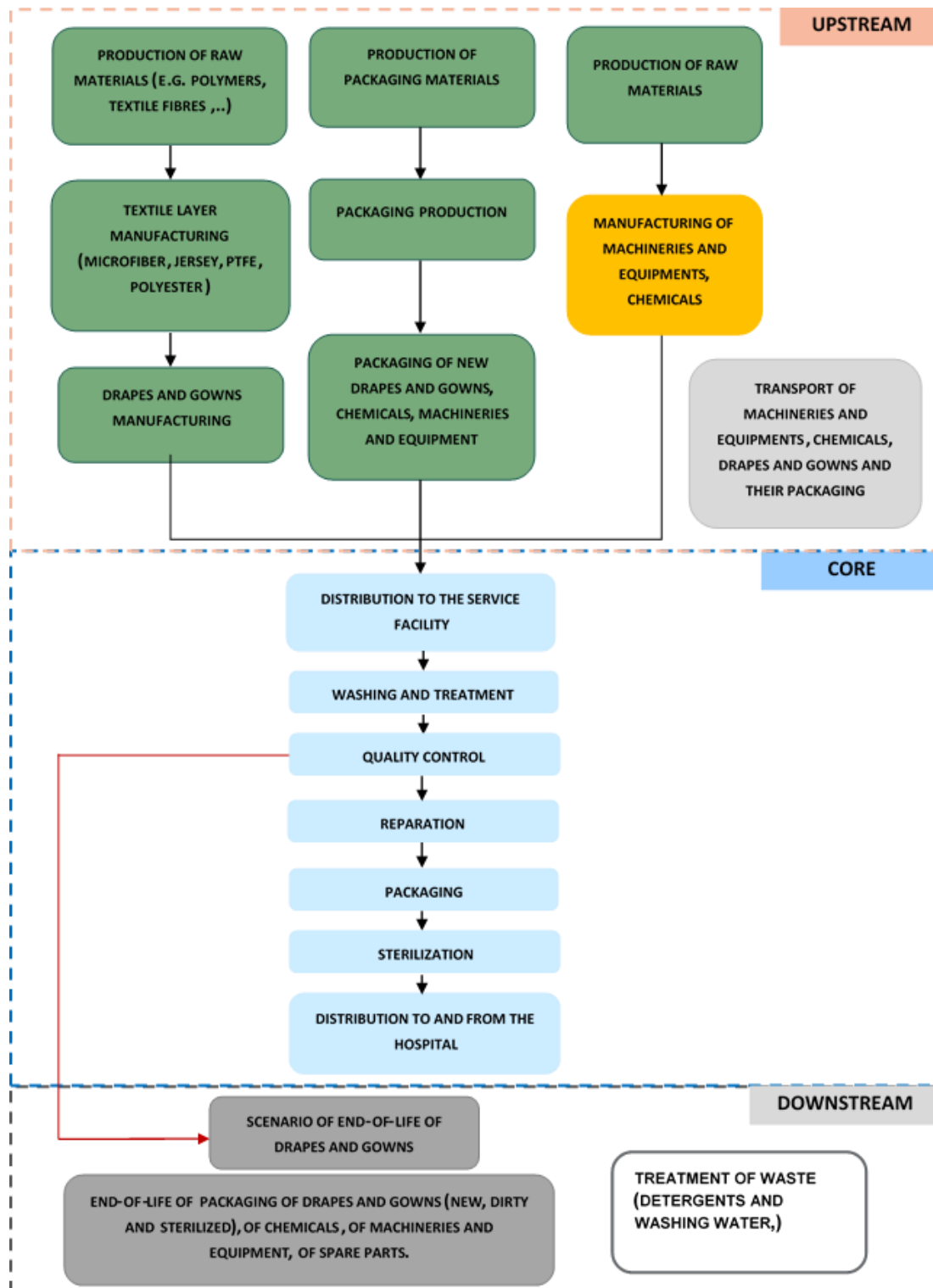


Figure 2 System diagram illustrating the processes that are included in the product system, divided into upstream, core and downstream processes.

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4.5 CUT-OFF RULES

Data for elementary flows to and from the product system contributing to a minimum of 99% of the declared environmental impacts shall be included (not including processes that are explicitly outside the system boundary as described in Section 4.3).

Deviations to the default maximum cut-off rule of 1% may be set in the PCR and shall be justified.

The check for cut-off rules in a satisfactory way is through the combination of expert judgment based on experience of similar product systems and a sensitivity analysis in which it is possible to understand how the un-investigated input or output could affect the final results.

4.6 ALLOCATION RULES

4.6.1 CO-PRODUCT ALLOCATION

The following step-wise procedure shall be applied for multifunctional products and multiproduct processes:

1. Allocation shall be avoided, if possible, by dividing the unit process into two or more sub-processes and collecting the environmental data related to these sub-processes.
2. If allocation cannot be avoided, the inputs and outputs of the system shall be partitioned between its different products or functions in a way that reflects the underlying physical relationships between them; i.e. they should reflect the way in which the inputs and outputs are changed by quantitative changes in the products or functions delivered by the system.
3. Where physical relationships alone cannot be established or used as the basis for allocation (or they are too time consuming), Table 1 shall be consulted for key processes. For processes not listed the most suitable allocation procedure shall be used and documented.

PROCESS	MAIN PRODUCT AND CO-PRODUCTS	ALLOCATION INSTRUCTION
The process of drapes and gowns production can produce also coproducts	Main product: washed and died textile Co-product: scrap of washed textile Co-product: scrap of died textile	Economic allocation
Incineration process	Main product: incineration function Co-products: electrical and thermal energies	Allocation of 100% attributed to the function

Table 1 Allocation procedure for key processes in the product system, if steps 1 and 2 are not possible.

If the economical 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 allocation method shall be justified and described in the LCA report.

4.6.2 REUSE, RECYCLING, AND RECOVERY

In the framework of the International EPD® System, the methodological choices for allocation for reuse, recycling and recovery have been set according to the polluter pays principle (PPP). This means that the generator of the waste shall carry the full environmental impact until the point in the product's life cycle at which the waste is transported to a scrapyard or the gate of a waste processing plant (collection site). The subsequent user of the waste shall carry the environmental impact from the processing and refinement of the waste but not the environmental impact caused in the "earlier" life cycles. See General Programme Instruction for further information and examples.

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4.7 DATA QUALITY REQUIREMENTS

An LCA calculation requires two different kinds of information:

- data related to the **environmental aspects** of the considered system (such materials or energy flows that enter the production system). These data usually come from the company that is performing the LCA calculation.
- data related to the **life cycle impacts** of the material or energy flows that enter the production system. These data usually come from databases.

Data on environmental aspects shall be as specific as possible and shall be representative of the studied process.

Data on the life cycle of materials or energy inputs are classified into three categories – specific data, selected generic data, and proxy data, 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, and data from other parts of the life cycle traced to the specific product system under study, e.g. materials or electricity provided by a contracted supplier that is able to provide data for the actual delivered services, transportation that takes place based on actual fuel consumption, and related emissions, etc.,
- **generic data** (sometimes referred to as “secondary data”), divided into:
 - **selected generic data** – data from commonly available data sources (e.g. commercial databases and free databases) that fulfil prescribed data quality characteristics for precision, completeness, and representativeness,
 - **proxy data** – data from commonly available data sources (e.g. commercial databases and free databases) that do not fulfil all of the data quality characteristics of “selected generic data”.

As a general rule, specific data shall always be used, if available, after performing a data quality assessment. It is mandatory to use specific data for the core processes as defined above. For the upstream processes, downstream processes, and infrastructure, generic data may also be used if specific data are not available.

Any data used should preferably represent average values for a specific reference year. However, the way these data are generated could vary, e.g. over time, and in such cases they should have the form of a representative annual average value for a specified reference period. Such deviations should be declared.

4.7.1 RULES FOR USING GENERIC DATA

The attributional LCA approach in the International EPD® System forms the basic prerequisites for selecting generic data. To allow the classification of generic data as “selected generic data”, they shall fulfil selected prescribed characteristics for precision, completeness, and representativeness (temporal, geographical, and technological), such as:

- the reference year must be as current as possible and preferably assessed to be representative for at least the validity period of the EPD,
- the cut-off criteria to be met on the level of the modelled product system are the qualitative coverage of at least 99% of energy, mass, and overall environmental relevance of the flows,
- completeness in which the inventory data set should, in principle, cover all elementary flows that contribute to a relevant degree of the impact categories, and
- the representativeness of the resulting inventory in the given temporal, technological, and geographical reference should, as a general principle, be better than $\pm 5\%$ of the environmental impact of fully representative data.

Section 4.8 provides a list of recommended databases/data sets to be used for generic data.

If selected generic data that meets the requirements of the International EPD® System are not available as the necessary input data, proxy data may be used and documented. The environmental impacts associated with proxy data shall not exceed 10% of the overall environmental impact from the product system.

The EPD may include a data quality declaration to demonstrate the share of specific data, selected generic data and proxy data for the environmental impacts.

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4.8 RECOMMENDED DATABASES FOR GENERIC DATA

Table 2 lists recommended databases for generic data. Please note that this listing does not imply that other data that fulfil the data quality requirements may not be used and that data quality assessment shall also be performed for the data sets in the recommended database by an LCA practitioner.

PROCESS	GEOGRAPHICAL SCOPE	RECOMMENDED DATASET	DATABASE
The database includes many processes related to the principal human activities	The database includes processes related to different geographical areas such as Europe (RER), Europe without Switzerland, the rest of the world (ROW) and many other countries	Energy, Transport, Material, Processing, Waste treatment	Ecoinvent 3

Table 2 Recommended databases for generic data.

4.9 IMPACT CATEGORIES AND IMPACT ASSESSMENT

The EPD shall declare the default impact categories as described in the General Programme Instructions. The characterisation models and factors to use for the default impact categories are available on www.environdec.com and shall be updated on a regular basis based on the latest developments in LCA methodology and ensuring the market stability of EPDs. The source and version of the characterisation models and the factors used shall be reported in the EPD. Alternative regional life cycle impact assessment methods and characterisation factors are allowed to 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.

The indicator Human toxicity should be mandatory added to calculate the impact on the Human health that is not yet considered. For the calculation of this damage can be used CML-baseline. This impact category is very important for processes that use Electric energy, transports and chemical materials for washing and sterilizing. Many LCA calculated with endpoint methods (Eco-Indicator 99, IMPACT 2002 and ReCiPe) demonstrate that the causes of damage indicated above influence the Human health.

4.10 OTHER CALCULATION RULES AND SCENARIOS

4.10.1 UPSTREAM PROCESSES

The following requirements apply to the upstream processes:

- Data referring to processes and activities upstream in a supply chain over which an organisation 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.
- The 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 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.
- For the electricity used in the upstream processes, electricity production impacts shall be accounted for in this priority when specific data are used in the upstream processes:

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1. Specific electricity mix as generated, or purchased, from an electricity supplier, demonstrated by a Guarantee of Origin (or similar, where reliability, traceability, and the avoidance of double-counting are ensured) as provided by the electricity supplier. If no specific mix is purchased, the residual electricity mix from the electricity supplier shall be used.³
2. National residual electricity mix or residual electricity mix on the market
3. National electricity production mix or electricity mix on the market.

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.

4.10.2 CORE PROCESSES

The following requirements apply to the core processes:

- 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 the electricity used in the core processes, electricity production impacts 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, where reliability, traceability, and the avoidance of double-counting are ensured) as provided by the electricity supplier. If no specific mix is purchased, the residual electricity mix from the electricity supplier shall be used⁴.
 2. National residual electricity mix or residual electricity mix on the market.
 3. National electricity production mix or electricity mix on the market.

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

- 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.
- Waste treatment processes of manufacturing waste should be based on specific data, if available.
- The lifetime of the machineries used for the washing and sterilization service activities shall be set at 20 years if no detailed information is provided by the manufacturer

4.10.3 DOWNSTREAM PROCESSES

The following requirements apply to the downstream processes:

- Data for the end-of-life stage are usually based on scenarios, but specific data should be used when available and relevant.
- Data on the pollutant emissions from the end-of-life 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.
- 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.

³ 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 of the electricity supplier.

⁴ 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 of the electricity supplier.

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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 via www.environdec.com

As a general rule the EPD content:

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

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

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 subject to the same verification procedure.

5.2 UNITS AND QUANTITIES

The following requirements apply for units and quantities:

- The International System of Units (SI units) shall be used, 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.
- Three significant figures⁵ should be adopted for all results, the number of significant digits shall be appropriate and consistent.
- 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.
- The result tables shall:
 - Only contain values or the letters “INA” (Indicator Not Assessed). It is not possible to specify INA for mandatory indicators. INA shall only be used for voluntary parameters that are not quantified because no data is available.⁶
 - Contain no blank cells, hyphens, less than or greater than signs or letters (except “INA”).

⁵ 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 $1.2 \cdot 10^2$ and $1.2 \cdot 10^{-2}$.

⁶ This requirement does not intend to give guidance on what indicators are mandated (“shall”) or voluntary.

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- 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 should 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 0)
- Content declaration (see Section 5.4.4)
- Environmental performance (see Section 5.4.5)
- Additional environmental information (see Section 5.4.6)
- References (see Section 5.4.9)

The following information shall be included, when applicable:

- Information related to Sector EPDs (see Section 5.4.7)
- 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 operator⁷,
- *Date of publication (issue): 20XX-YY-ZZ,*
- *Date of revision: 20XX-YY-ZZ, when applicable,*
- *Date of validity: 20XX-YY-ZZ*

⁷ 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.

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- 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,

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 mandatory statement from ISO 14025: “EPDs within the same product category but from different programmes may not be comparable.”
- A statement that the EPD owner has the sole ownership, liability and responsibility of the EPD
- Information about verification⁸ and reference PCR in a table with the following format and contents:

Product category rules (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>
Independent third-party verification of the declaration and data, according to ISO 14025:2006: <input type="checkbox"/> EPD process certification <input type="checkbox"/> EPD verification
Third party verifier: <name, organisation and signature of the third party verifier> <i>In case of certification bodies:</i> Accredited by: <name of the accreditation body and accreditation number, if applicable>. <i>In case of individual verifiers:</i> Approved by: The International EPD® System Technical Committee, supported by the Secretariat
Procedure for follow-up of data during EPD validity involves third party verifier: <input type="checkbox"/> Yes <input type="checkbox"/> No

The following information is mandatory to include in the EPD:

- A statement that “The comparison of different EPDs shall be carried out taking into account”:
 - **in the same PCR:**
 - the criteria to define the functional unit and their method of calculation,
 - the total number of cycles of life of drapes and gowns and their method of calculation,
 - the total number of cycles of life of drapes and gowns in one year and their method of calculation.
 - **in the comparison of one disposable drape and one reusable drape:**
 - one type of drape should be chosen,
 - 1 kg of this drape should be calculated taking into account of the percentage of its component materials,

⁸ 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.

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- the life cycle should be calculated considering one cycle of sterilization.

5.4.3 SERVICE INFORMATION

The service information section of the EPD shall include:

- Address and contact information to EPD owner,
- Description of the organisation. This may include information on service- 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 service site,
- Service identification by name, and an unambiguous identification of the service by standards, concessions or other means,
- Identification of the service according to the UN CPC scheme system. 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 Services by Activity (NACE/CPA) or
 - Australian and New Zealand Standard Industrial Classification (ANZSIC),
- Description of the service, its application
- Geographical scope of the EPD, i.e., for which geographical location(s) the service's performance has been calculated,
- Functional unit or declared unit,
- Reference service life (RSL), if applicable,
- 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,
- Description if the EPD system boundary is "cradle-to-gate", "cradle-to-gate with options" or "cradle-to-grave",
- Information on which life cycle stages are not considered (if any), with a justification of the omission,
- 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,
- Additional information about the underlying LCA-based information, such as assumptions, cut-off rules, data quality and allocation.

5.4.4 CONTENT DECLARATION

A content declaration is not relevant for a PCR of a service.

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5.4.5 ENVIRONMENTAL PERFORMANCE

5.4.5.1. Environmental impacts

The indicators related to potential environmental impact listed in Table 3 shall be declared per functional unit or declared unit, and per life cycle stage.

PARAMETER		UNIT	UPSTREAM	CORE	DOWNSTREAM	TOTAL
Global warming potential (GWP)	Fossil	kg CO ₂ eq.				
	Biogenic	kg CO ₂ eq.				
	Land use and land transformation	kg CO ₂ eq.				
	TOTAL	kg CO ₂ eq.				
Acidification potential (AP)		kg SO ₂ eq.				
Eutrophication potential (EP)		kg PO ₄ ³⁻ eq.				
Formation potential of tropospheric ozone (POCP)		kg C ₂ H ₄ eq.				
Abiotic depletion potential – Elements		kg Sb eq.				
Abiotic depletion potential – Fossil fuels		MJ, net calorific value				
Water scarcity potential		m ³ eq.				
Human toxicity 100a		kg 1,4-DB eq				

Table 3 Indicators describing potential environmental impacts⁹.

Notes:

- Abiotic depletion potential is calculated and displayed as two separate indicators. ADP-fossil fuels include all fossil resources, while ADP-elements include all non-renewable material resources.

5.4.5.2. Use of resources

The indicators for resource use based on the life cycle inventory (LCI) listed in Table 4 shall be declared per functional unit or declared unit, and per life cycle stage.

PARAMETER		UNIT	UPSTREAM	CORE	DOWNSTREAM	TOTAL
Primary energy resources – Renewable	Use as energy carrier	MJ, net calorific value				
	Used as raw materials	MJ, net calorific value				
	TOTAL	MJ, net calorific value				
Primary energy resources – Non-renewable	Use as energy carrier	MJ, net calorific value				

⁹ Please check www.environdec.com for the latest list of default impact categories, units and characterisation factors as they may have been updated compared to this table.

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PARAMETER		UNIT	UPSTREAM	CORE	DOWNSTREAM	TOTAL
	Used as raw materials	MJ, net calorific value				
	TOTAL	MJ, net calorific value				
Secondary material		kg				
Renewable secondary fuels		MJ, net calorific value				
Non-renewable secondary fuels		MJ, net calorific value				
Net use of fresh water		m ³				
Toxic materials		kg				

Table 4 Indicators describing use of primary and secondary resources.

Notes:

- In order to identify the primary energy used as an energy carrier (and not used as raw materials), the parameter may be calculated as the difference between the total input of primary energy and the input of energy resources used as raw materials.
- Energy content of biomass used for feed or food purposes shall not be considered.
- The net use of fresh water does not constitute a “water footprint” as potential environmental impacts due to the water use in different geographical locations is not captured. For this indicator:
 - Evaporation, transpiration, product integration, release into different drainage basins or the sea, displacement of water from one water resource type to another water resource type within a drainage basin (e.g. from groundwater to surface water) is included.
 - In-stream water use is not included.
 - For water used in closed loop processes (such as cooling system) and in power generation only the net water consumption (such as reintegration of water losses) should be considered.
 - Seawater shall not be included
 - Tap water or treated water (e.g. from a water treatment plant), or wastewater that is not directly released in the environment (e.g. sent to a wastewater treatment plant) are not elementary water flows, but intermediate flows from a process within the technosphere.
 - Additional transparency in terms of geographical location, type of water resource (e.g. groundwater, surface water), water quality and temporal aspects may be included as additional information.
 - The following indicators per declared unit shall be reported in the EPD: Toxic materials used in the core module. All the materials that the safety sheet declares as toxic should be specified.

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 General Programme Instructions. When the amount of waste or the output flows from the life cycle inventory (LCI) are declared, the indicators in Table 5 and Table 6 shall be reported per functional unit or declared unit, and per life cycle stage.

PARAMETER	UNIT	UPSTREAM	CORE	DOWNSTREAM	TOTAL
Hazardous waste disposed	kg				
Non-hazardous waste disposed	kg				
Radioactive waste disposed	kg				

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Table 5 Indicators describing waste production.

PARAMETER	UNIT	UPSTREAM	CORE	DOWNSTREAM	TOTAL
Components for reuse	kg				
Material for recycling	kg				
Materials for energy recovery	kg				
Exported energy, electricity	MJ				
Exported energy, thermal	MJ				

Table 6 Indicators describing output flows.

Notes:

- The parameters are calculated on the gross amounts leaving the system boundary of the system in the LCI. If e.g. there is no gross amount of "exported energy, electricity" leaving the system boundary, this indicator is set to zero,
- The parameter "Materials for energy recovery" does not include materials for waste incineration. Waste incineration is a method of waste processing, when $R1 < 60\%$ (European Guideline on R1 energy interpretation), and is allocated within the system boundary.
- In case there are never any flows of these types leaving the system boundary for a product category, the indicators may be removed by the PCR.

5.4.5.4. Other environmental indicators

The reference PCR may add other environmental indicators to include for the product category from the inventory or impact assessment. Such indicators should be based on international standards or similar methodologies developed in a transparent procedure. Reference to the chosen indicators and methodologies shall be reported.

5.4.6 ADDITIONAL INFORMATION

5.4.7 INFORMATION RELATED TO SECTOR EPDS

For sector EPDs, the following information shall also be included:

- 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.

5.4.8 DIFFERENCES VERSUS PREVIOUS VERSIONS

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

- a description of the differences versus previously published versions, e.g. a description of the percentage change in results and the main reason for the change;
- a revision date on the cover page

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5.4.9 REFERENCES

This section shall include a list of references, including the General Programme Instructions (including version number), standards and PCR (registration number, name and version).

5.4.10 EXECUTIVE SUMMARY IN ENGLISH

For EPDs published in another language than English, an executive summary in English shall be included.

The executive summary should contain relevant summarised information related to the programme, product, environmental performance, additional information, information related to sector EPDs, references and differences versus previous versions.

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6 GLOSSARY

CO ₂	Carbon dioxide
CPC	Central product classification
EPD	Environmental product declaration
ISO	International Organization for Standardization
kg	kilogram
LCA	Life cycle assessment
PCR	Product Category Rules
SI	The International System of Units
SO ₂	Sulphur dioxide
UN	United Nations

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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.

EPD International (2017) General Programme Instructions for the International EPD® System. Version 3.0, dated 2017-12-11.
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 (2017), ISO 21930:2017, Sustainability in buildings and civil engineering works -- Core rules for environmental product declarations of construction products and services

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8 VERSION HISTORY OF PCR

VERSION 1.0, 2018-08-15

Original version of the PCR.

VERSION 1.01, 2019-09-06

- Clarified terms of use
- Editorial changes

VERSION 1.02, 2020-03-04

- Cover image added

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