Product-Category Rules (PCR)

for Preparing an Environmental Product Declaration (EPD) for

Medical Electrical Equipment – Non-invasive Sphygmomanometers

PCR 2014:1.0

AViTA Corporation

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1. General Information

This document is to be used as the product category rules (PCR) for the manufacturing of medical electrical equipment – non-invasive sphygmomanometers ("product") globally. This PCR covers products with the following Harmonized System (HS) Codes/CCC Codes: 90189010. The requirements specified in this PCR are intended to be used for EPDs certified in accordance with the ISO 14025 standard. This document shall be valid until December 31, 2017.

This PCR was first drafted by the AViTA Corporation. Representatives from major Taiwanese manufacturers of similar products and stakeholders were invited by the Taiwan Electrical and Electronic Manufacturers' Association(TEEMA) to the open consultation meeting held on November 10, 2014, to participate in the discussion and review of this PCR. The Environment and Development Foundation (EDF) subsequently reviewed and approved this PCR.

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2. Company and product description

The EPD shall include information about the manufacturing company/organization. The information may include manufacturing process related information, and environmental related information, such as the environmental management system information. The information may also include special issues which the company/organization would like to emphasize, such as the products meeting certain environmental criteria, or environmental safety and health related information.

This PCR is applicable to both Business-to-Business (B2B) and Business-to-Consumer/Customer, (B2C) communications. During the inventory of product related environmental impacts, the scope of inventory shall cover both the product and its packaging.

2.1 Product group function

The non-invasive sphygmomanometer products make use of the oscillometric method to retrieve the pulse signals from human body to measure and calculate the blood pressure. The measure results, including information such as systolic pressure, diastolic pressure, and pulse are then display on an LCD screen. The products covered by this PCR do not include wearable devices, such as a sports watch not using the oscillometric method to measure blood pressure.

2.2 Product components/compositions

The product's main components included the following:

1. Motherboard (Main Board)

2. Electronic components: e.g., MCU, memory, control chip, Bluetooth module, built-in antenna module, NFC, etc.

3. Pressure sensing unit: e.g., pump, discharge valve, etc.

4. LCD display

5. Power section: e.g., battery, booster circuit, transformer, etc.

6. Configuration components: e.g., housing, wrist/arm band (cuff), etc.

7. Packaging: e.g., storage box or case

8. Other elements/components: e.g., documentation CD, user manual, flash drive, memory card, etc.

The data quality requirements for the main components are described in Section 9 on calculation rules and data quality requirements. The EPD shall also include the other components of the product, but their data quality requirements are different from those of the main components.

2.3 Product technical description

The product technical description part of the EPD may include but not limited to the following information:

1. Product name and model number
2. Device total weight and dimensions
3. Measurement range: e.g., 30~280mmHg
4. Accuracy calibration: e.g., ±3mmHg
5. Operation environment: e.g., 10~40℃; 15~95% RH(non-condensing)
6. Power supply: e.g., DC 3V or 6V; AC 100V~240V
7. Cuff specification

3. List of materials and chemical substances

The contents of the following materials and substances in the product shall be declared:

- All materials of the product (excluding packaging material) with weight ratio (material weight/product weight (excluding packaging)) ≥ 1%;
- All materials of the packaging with weight ratio (material weight/packaging weight) ≥ 1%;
- All substances/materials in the product restricted/regulated by legal and customer requirements; and
- The following materials in the main components: flame retardants, lead content in solder, lead and flame retardant content in solder masking agent, and substances regulated by EU's RoHS Directive (the latest version).

The declaration of halogen-free flame retardants, lead-free solders and no RoHS-regulated substances may only be made when appropriate evidences are available (for example, test reports from accredited laboratories/testing facilities). The following organizations may provide accreditation for testing facilities: Taiwan Accreditation Foundation (TAF), (Asia Pacific Laboratory Accreditation Cooperation (APLAC), International Laboratory Accreditation Cooperation (ILAC) or ILAC Mutual Recognition Arrangement (ILAC MRA). For definitions of testing methodology and confirmations of regulated hazardous substances based on the accredited laboratories' product testing methods, please refer to IEC 62321 Standard.

4. Declared unit

The declared unit is one (1) unit of non-invasive sphygmomanometer, with the declaration of product type (e.g. wrist or arm type). The reason for adopting this unit is that the product is sold and marketed in this unit.

5. System boundaries

The main system boundaries for the declared product system are presented as follows:

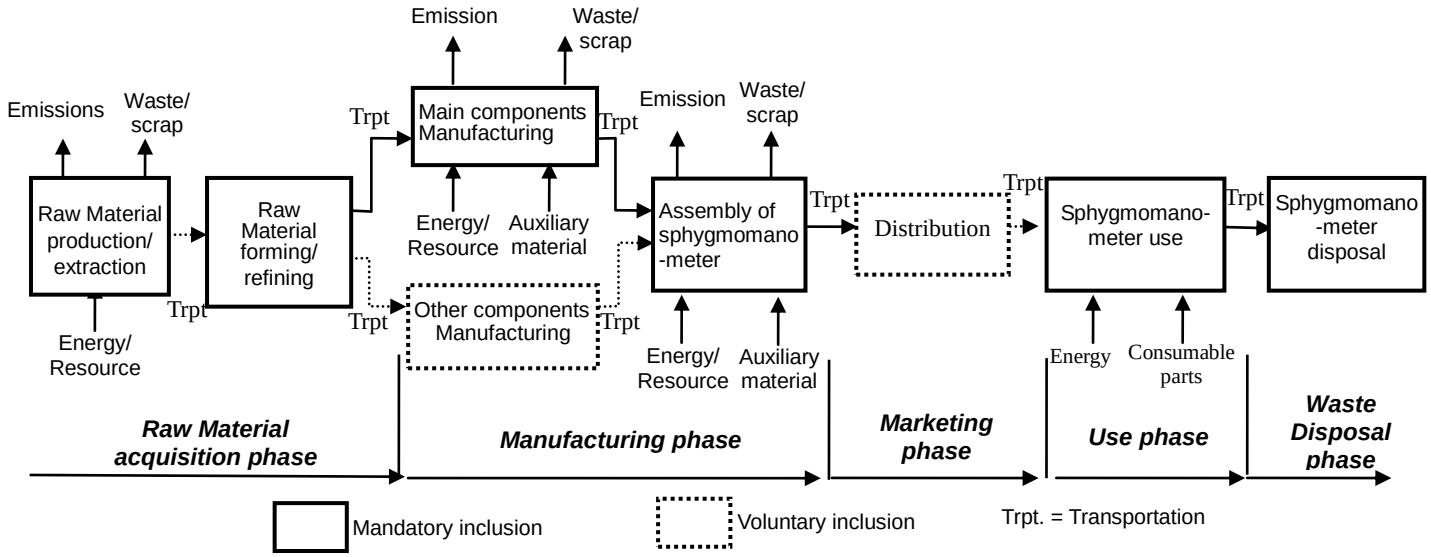

Figure 1 System boundary of the product system

As noted in Figure 1 above, the life cycle of a non-invasive sphygmomanometer covers five life cycle stages: raw material acquisition, product manufacturing, distribution and marketing, product use and recycling/end-of-life. The data quality requirements for the main components and other components are described in Section 9 on calculation rules and data quality requirements.

Raw Materials Acquisition Stage

The LCA shall include information for the following unit processes:

— Raw material extraction/production and manufacturing of main components and other

components;

- Raw material refining/forming and transportation of raw materials;
- Production/generation of energy used for raw material manufacturing.

Manufacturing Stage

The LCA shall include information for the following unit processes:

- Manufacturing of main components and transportation of process waste to the waste treatment facilities;
- Transportation of main components to the product assembly plant;
- Assembly of products and transportation of process waste to the waste treatment facilities.

The inclusion in the LCA the information on the input/output of packaging material during main components manufacturing process and the manufacturing of minor/secondary components/parts is optional (voluntary).

Distribution and Marketing Stage

The LCA shall include information for the following unit processes:

- Transportation of products to the distribution sites or customer designated locations;
- Inventory and reporting of energy/resource input and waste generation during the marketing process is optional (voluntary);
- Inventory and reporting of transportation from sales/distribution sites to users is optional (voluntary).

Use Stage

The power consumption of the non-invasive sphygmomanometer during the use stage can be calculated for the assumed usage scenario with the following assumptions:

1. The product has a usage life of 2 years.

2. The product is being used three times a day, for a total of 1095 times a year, and the operating time for each use is 2 minutes.

Product's life-time operation time = 2 (year) X 1095 (time/year) X 2 (min) / 60 (min/hr) = 73 hours

3. The product uses a DC power supply (primary battery).

The number of disposable batteries used during product life-time = 2 year X 1095 time / (number of use each new battery can provide X number of new batteries installed)

The battery life is tested using new batteries. Determine the number of product uses for newly installed battery until the product stop operation (battery depleted), with the following results:

- For arm-type product, the product's POWER button will stop functioning when the battery voltage drops below 4.6V ± 0.2V or pumping voltage below 3.5V ± 0.2V. A typical battery can be used for 350 times.
- For wrist-type product, the product's POWER button will stop functioning when the battery voltage drop below 2.4V ± 0.2V or pumping voltage below 1.6V ± 0.2V. A typical battery can be used for 250 times.

4. Total DC power consumption during use stage (kWh) = number of batteries used X battery voltage (V) X battery current (A) X Total operating time (h)

5. If the product is powered by an AC power supply, its working states can be defined as: On mode, Off Mode and Standby Mode. Each mode is defined as follows:

- On Mode): The state when operating system and other software have completed loading, user profile has been established, and the system operated under the preset basic applications after system initiation. Assume usage of three times a day, two minutes each time, for a total of 2190 minutes per year.
- Off Mode: The state when the product is turned off. This state is not included in the calculation for this PCR.
- Standby Mode: The state after the product has completed its operation, is in idle state, and the screen and all relevant indicators are off until the next use. With the exception of time for On Mode, all remaining time are in Standby Mode, for a total of 523,410 minutes per year.

The estimated annual product usage time is calculated as follows:

Usage Mode	Usage time (min)	Usage hour (h)
ON mode	2190	36.5
Standby mode	523410	8723.5
Off mode	0	0

Therefore, the total electricity consumption during product's use stage (kWh) = 2 years X (total electricity consumption during On Mode + total electricity consumption during Standby Mode)

= 2 (year) x (36.5 hr) X On Mode power (W) + 8723.5 (hr) X Standby Mode power (W)) / 1000

6. If the product can use both AC and DC power supply, calculate the use stage power consumption based on the DC power supply mode only.

7. The declaration of maintenance during the use stage, and transportation of end-of-life products to the waste disposal system is mandatory, so the actual consumption of batteries and other consumables during the use stage shall be included in the inventory process.

8. If there are other definitions or scenarios of product energy use, it shall be explained in the declaration.

Recycling/end-of-life Stage

Reporting of recycling information (such as recycling and dis-assembly report or information on recycling channels) is mandatory in the EPD

5.1 Specification of different boundary settings

Boundary in time

The validity period for the LCA results presented in the LCA report shall be defined.

Boundary towards nature

If the manufacturing processes are located within Taiwan, the solid waste categories as defined in Taiwan's Waste Disposal Act shall be adopted. If the processes are located in other countries, equivalent legal requirements shall be considered.

The natural boundary of the system shall describe the boundary where the materials and energy resources flow from nature into the system, and where the water and air emissions and waste are released out of the system.

Only the quantity of the disposed waste needs to be considered; landfilling process does not need to be considered. If the waste is generated through wastewater treatment or incineration process, such waste should be included into the wastewater treatment or incineration process.

Boundaries in the life cycle

The boundaries in the product life cycle are described in Figure 1. The construction of the site and infrastructure, as well as the production of manufacturing equipment do not need to be included.

Boundaries towards other technical systems

Boundaries towards other technical systems describe the inputs of material and other components towards other systems, as well as outputs of materials towards other systems. For the inputs of recycled materials and energy towards the product manufacturing stage, the transportation between the recycling process and use of recycled materials shall be included in the data set. For the production of recyclable products during the manufacturing stage, the transportation towards the recycling process shall be included.

(Note: Further explanations are provided in Section 7 on open-loop recycling.)

Boundaries regarding geographical coverage

The manufacturing stage may cover manufacturing processes located on any sites around the world. For processes located in a specific region, the data used should be representative of the region. The data for the main constituents shall be the specific regional data for the region where the process takes place (see Section 9). For ease of comparison, no matter where the emissions are generated, the same environmental impact parameters should be used for life cycle impact assessment (see Section 10).

6. Cut-off rules

For any impact category, if the sum of various impacts from a specific process/activity is less than 1% of the impact equivalent in that category, such a process/activity may be neglected during the inventory analysis. Nonetheless, the accumulated impact of neglected process/activity may not exceed 5%. Components and materials omitted from the LCA shall be documented.

(Note: This judgment for this "1% Rule" is based on the environment relevance assessment of material input to the system, and does not consider special and exceptional environmental impacts.)

7. Allocation rules

The main allocation rules shall be valid for the entire product system. For other secondary processes, other allocation rules may be defined; however, the use of these rules should be justified. Product-specific information should be preferentially collected in order to avoid the need for allocation. While selecting allocation rules, the following principles are recommended.

- Multi-output: The allocations are based on the changes in the resource consumption and pollutant emissions (for example, adopted quantity allocation for some main component, or surface allocation for some components), following the changes in the studied system's output product or function or economical relationship.
- Multi-input: The allocation is based on actual relationship. For example, the manufacturing process's emissions may be affected by the change in waste flow input.
- Open loop recycling: For the input of recycled materials or energy during the manufacturing stage of the product system, the transportation between the recycling process and the recycling to material use shall be included in the dataset. For the product which shall be recycled during the manufacturing stage, the transportation towards the recycling process shall be included.
- Closed loop recycling: For materials from the product system that are being recycled and reused within the same product system, the recycling ratio shall be considered to avoid double counting. The transportation and energy inputs from the recycling process to the reuse of materials shall be included in the dataset. For the product which shall be recycled during the manufacturing stage, the transportation towards the recycling process shall be included.

Notes:

- *Allocation may be avoided through avoidance of dividing processes, for example as described in Section 6.3 of ISO/TR 14049; or through expansion of system boundary (for example as described in Section 6.4), so that the amended system shares the same product exchanges as the original system.*

8. Units

The base units and derived units of the International System of Units (SI, Système International

d'unités) shall be used preferentially.

Power & energy units:

- power unit: W
- energy unit: J

Specification units:

- length unit: m
- capacity unit: m^3
- area unit: m^2
- weight unit: kg

If necessary, prefixes may be used before the SI units:

10^9 = giga, symbol “G”
10^6 = mega, symbol “M”
10^3 = kilo, symbol “k”
10^{-2} = centi, symbol “c”
10^{-3} = milli, symbol “m”
10^{-6} = micro, symbol “μ”
10^{-9} = nano, symbol “n”

9. Calculation rules and data quality requirements

Data quality requirements for the raw material acquisition stage

- Generic data may be used for the acquisition, production, forming and refining of raw materials used for the components of the products. Please refer to Appendix I for the common sources of generic data.

Data quality requirements for the manufacturing stage

- Site specific data (for example, specific data for manufacturing plant or transportation) shall be used for the manufacturing and assembly of major components. If other types of information are used, description of the information and rationale for using the information shall be provided. For site specific data of main component manufacturing plants, specific data from a plant representative of such a site may be used.
- Generic data may be used for the manufacturing of other components for the products, and based the calculation on actual consumption. Please refer to Appendix I for the common sources of generic data.
- When generic data are used, the equivalence between the chemical and/or physical process of referred systems shall be considered. Moreover, it is also recommended to consider the date or geographic aspects of the data quality when feasible.
- Generic data may also be used when suppliers refuse to provide specific data, or when even if generic data are used in place of specific data, there is only minor impact to the results. The general rule is that if generic data are used in place of specific data, their combined contribution for all life cycle stages shall not be greater than 20% of total impacts for each impact category. But there may be certain exception to specific products, and such exceptions shall be explained.

- The data shall be representative for the average of a specific year. If the average data for a specific time period of less than one year is used, the reason for using such data shall be provided.
- The electricity mix for the manufacturing stage should be site specific data. If site specific data cannot be obtained, the official electricity mix for the country where the site is located may be used as approximate value. The electricity mix should be documented.
- For the definition of hazardous waste, the definition as defined in Taiwan's Waste Disposal Act shall be used for sites located in Taiwan. For sites located outside Taiwan, legal requirements for the host country shall be observed.
- For the transportation of main components to the manufacturing plant, the actual transportation modes used and distance traveled shall be considered.

Data quality requirements for the distribution and marketing stage

- For transportation of products to the distributors or points-of-sales, the actual mode of transportation and distance traveled shall be considered.

Date quality requirements for the use stage

- The energy consumption of the product shall be determined based on testing methodology stipulated in applicable international, national or industrial standards of the countries/regions the product is marketed.
- For the electricity mix for the use stage, the official electricity mix for the country where the product is exported may be used as approximate value or generic data. Please refer to Appendix I for the common sources of generic data.

Date quality requirements for the recycling/end-of-life stage

- For transportation of end-of-life product as post-consumer waste for delivery to processors or recyclers, the data from national or industry sources or consumer behavior surveys can be used. When such data cannot be obtained, evaluation based on assumed scenario can be made, and the assumptions for such a scenario shall be reported in the EPD.

- Generic data may be used during the recycling/end-of-life stage, if for specific reason the site specific data for the recycling/waste disposal system cannot be obtained. Then generic data and recycling rate may be used to calculate environmental impact. Please refer to Appendix I for the common sources of generic data.

10. Parameters to be declared in the EPD

The following parameters shall be declared in the EPD:

Resource use

- non-renewable resources
    - materials resources
    - energy resources (used for energy conversion purposes)

- renewable resources
    - material resources
    - energy resources (used for energy conversion purposes)
- secondary resources
    - material resources (pre-consumer or post-consumer recycling and reuse)
    - energy resources (used for energy conversion purposes)
- recovered energy flows (such as thermal energy) expressed in MJ
- water use divided into:
    - total amount of water (consider make-up water for in-plant recycling and reuse)
    - direct amount of water used by the core process

The following requirements on the resource declaration also apply:

- all parameters for resource consumption shall be expressed in mass, with the exception of renewable energy; resources used for the generation of hydroelectric, wind electricity and solar energy, which shall be expressed in MJ;
- all parameters shall not be aggregated but reported separately. Resources which contribute for less than 5% in each category shall be included in the resources list as "other";
- nuclear power shall be reported among the non-renewable energy resources as kg of uranium calculated by converting the thermal energy (MJ) considering a reactor of III generation with an efficiency of 33%;
- the PCR can define other resources (for example rare materials originating from the LCI data) which may be listed and detailed in the EPD for each specific product category;
- the energy content into some products (such as paper or plastic based products) is useful information for the end of life management. For this reason, the "energy content of product" shall be declared 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);
- energy content of biomass used for feed or food purposes shall not be considered.

Impact equivalents expressed as potential environmental impacts

The potential environmental impacts associated with the various types of use of resources and pollutant emissions shall be reported into the following impact categories:

- Emission of greenhouse gases (expressed as the sum of global warming potential, GWP, 100 years, in CO2 equivalents).
- Emission of acidifying gases (expressed as the sum of acidifying potential in sulphur dioxide (SO2) equivalents).
- Emission of gases that contribute to the creation of ground-level ozone (expressed as the sum of ozone-creating potential, ethene-equivalents).
- Emission of substances to water contributing to oxygen depletion (expressed as phosphate (PO4) equivalents).

Impact categories for optional declaration

- Emission of ozone-depleting gases (expressed as the sum of ozone-depleting potential in mass of CFC 11-equivalents, 20 years).

Waste

- hazardous waste (as defined in Taiwan's Waste Disposal Act, or follow host countries' laws for sites outside Taiwan).
- non-hazardous waste

Note: For characterization factors of each impact category, please refer to *General Programme Instructions For The International EPD System, Version 2.01 (2013-09-18).*

11. Recycling information

The recycling information shall include information such as dis-assembly instructions, which parts/components are suitable for recycling (such as metal cases) or not suitable for recycling. The information which the EU WEEE Directive requires the end product manufacturer to provide may also be included in the declaration information for products.

If practical, information for the parts which cannot be recycled and therefore should be disposed of properly during the end-of-life stage may also be included.

Recycling marking for product's plastic components and plastic packaging material (optional information):

- Plastic parts marking: Where technologically possible, plastic parts of the product weighing $\geqq$ 25 g shall be marked in accordance with the ISO 11469 and ISO 1043 Part 1/2/3/4, SPI or other international standard label to facilitate their identification and recovery at the end of life.
- Plastic packaging material marking: The Plastic packaging materials shall be labeled on the parts with SPI or other international standards for ease of sorting.

12. Other environmental information (Optional)

The EPD may cover information including technology adopted, site of product manufacturing and assembly, as well as information on other working environment, health and risk-related aspects.

If this PCR is to be used for product carbon footprint declaration purpose, in the declaration, information regarding commitment on GHG reduction should be included and shall ensure that the commitment is measurable, reportable and verifiable. The organization may also list environmental and energy management related information, such as awards, commendations and system certifications (e.g., ISO 14001, ISO 14064-1, IECQ HSPM) etc.

13. Information about the certification

The information on PCR review, EPD verification and verification organization shall be included.

EPD Certification is valid until 20XX-__-__ According to the Requirements for the international EPD system, *General Programme Instructions, Version 2.01 (2013) – www.environdec.com.* The PCR review for _____ (PCR 2014:) was administered by the Environment and Development Foundation and carried out by an LCA expert panel chaired by Dr. Wen-Ching Chen (wencc@edf.org.tw). Independent verification of the declaration, according to ISO 14025:2006 □ Internal ■ External
Third party verifier: Environment and Development Foundation in Taiwan. Accredited by : Name: Title: Organization: Signature:_____ Name: Title: Organization: Signature:_____ Name: Title: Organization: Signature:_____
Environmental declarations from different programmes may not be comparable.

14. References

The EPD shall refer to the following documents:

- GENERAL PROGRAMME INSTRUCTIONS FOR THE INTERNATIONAL EPD® SYSTEM, Version 2.01 (2013-09-18), downloadable from: http://www.environdec.com/Documents/GPI/General_programme_instructions_2_01_20130918.pdf
- Relevant PCR documents
- The underlying LCA report

When available, the following documents shall also be referenced:

- Other documents and recycling instructions that verify and complement the EPD.

- ISO 14971:2012 Medical Devices Risk Management, ISO, 2012

Appendix I – Generic Data Sources to Refer to

For processes located within Taiwan, Taiwan generic data or the data published by the commercial, industrial and energy competent authorities of the Republic of China (ROC) government, may be used. However, for other regions (such as EU), if there are more relevant generic data available, these data should be used instead. Data from the following generic databases are recommended for use.

Material	Database
Packing materials, transport, Waste treatments	BUWAL 250
Steel, Primary copper, Copper products, Electricity, Fuels, Aluminum, Chemicals, Transports, Waste management	ELCD
	EIME (Environmental Information and Management Explorer) EcoBilan
Plastics	PE Plastics Europe (Association of Plastics Manufacturers in Europe)
	ELCD
	EIME (Environmental Information and Management Explorer) EcoBilan
Electronic components	ELCD
	EIME (Environmental Information and Management Explorer) EcoBilan
General Database	Ecoinvent
	The Boustead Model
	PE-GaBi
	DoITPro(Taiwan)

Appendix II – Reporting Format for the EPD

This appendix provides guidance information for the titles of sections, types of data and required information to be reported in the mandatory reporting part of the EPD. As a generic reporting template, the following titles and sub-titles are recommended:

(Refer to the PCR manual for the section numbering, the information in Italics are the recommended data/information for inclusion)

Introductory part

Each EPD should have an introduction part on the top part of the EPD which includes the following information:

- *Company/organization name*
- *Product name*
- *EPD registration number*

Description of the company/organization and product/service

Company/Organization

- *Description of company/organization*
- *Description of overall working environment, existing quality system and environmental management system*

Product and services (see Section 2)

- *Product's main applications*
- *Description of product specification, manufacturing process, manufacturing sites (if there are several sites)*
- *For product's environmental performance aspects, characteristics which may improve the usefulness of product*
- *Other types of relevant information, for example, special manufacturing processes with special advantages to the environment*

List of materials and chemical substances

- *Content declaration (see Section 3)*

Presentation of the environmental performance

- *Outline of the LCA methodology, for example, period of LCA, declared units, system boundaries (graphical presentation), cut-off and allocation rules, and data sources.*

Manufacturing stage *(see Section 10)*

Use stage *(see Section 10)*

- *Geographical region for product delivery*
- *Transportation data*
- *End-of-life information*

Information about Company and Certification Organization

Recycling information *(see Section 11)*

Other environmental information *(see Section 12)*

Information regarding certification *(see Section 13)*

- *Names of certification and verification organizations*
- *Validity of certification certificates*
- *Compliance with legal and relevant requirements*

References *(see Section 14)*

- *relevant PCR documents*
- General Programme Instructions for the International EPD® System, Version 2.01 (2013-09-18)
- *underlying LCA study*
- *other supporting documents for LCA information*
- *other relevant documents regarding company/organization's environmental activities*

Appendix III Abbreviations

Acronym	Common Name
PCR	Product Category Rule
EPD	Environmental Product Declaration
RoHS	The Restriction of the use of certain Hazardous Substances in electrical and electronic equipment
TAF	Taiwan Accreditation Foundation
APLAC	Asia Laboratory Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
ILAC MAR	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
Trpt	Transportation
LCA	Life Cycle Assessment
ErP	Energy Related Product
WEEE	The Waste Electrical and Electronic Equipment Directive
SPI	Society of the Plastics Industry
ISO	International Organization for Standardization
CFP	Carbon Footprint of Product
TEC	Typical Energy Consumption