

Luxembourg, 27 October 2017

# **Environmental and Social Data Sheet**

# **Overview**

Proiect Name:	PHILIPS MEDTECH R&D
Project Number:	2017-0471
Country:	Netherlands
Project Description: development in the area of heal	Financing of Philips' expenditure on research and the theorem technology.
EIA required:	no

Project included in Carbon Footprint Exercise<sup>1</sup>: no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

# **Environmental and Social Assessment**

## Environmental & Social Assessment

The project's R&D activities are a central part of the promoter's operations and will be embedded in the existing organisational and management structure. The project will not result in any residual environmental impact as it will be carried out in existing and authorised research facilities. The operating procedures in place are in line with best industry standards and are regularly audited externally.

The research activities undertaken in the project are aimed to result in new and improved medical devices with a positive impact on healthcare quality. Therefore, the project, if successful, is expected to bring positive social impact.

## **Other Environmental and Social Aspects**

The project will be managed and carried out by the promoter's existing R&D staff in the Netherlands (Eindhoven).

Philips complies with the following the governmental agencies and quality system regulations:

- The International Standards Organisation EN ISO 13485:2003, Medical devices Quality management systems;
- The independent certification body DEKRA acts as Philips' notified body to ensure that the manufacturing quality systems comply with ISO 13485:2003;
- The European Council Directives 93/42/EEC and 90/385/EEC, which relate to medical devices and active implantable medical devices.

<sup>&</sup>lt;sup>1</sup> Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.



Luxembourg, 27 October 2017

In addition, Philips utilises environmental management systems and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations, notably:

- The US Environmental Protection Agency for the regulation of environmental and employee health and the US Occupational Health and Safety Assessment System;
- The European Union Registration, Evaluation, Authorisation and Restriction of Chemicals;
- The ISO 14001 environment management certification (82% of manufacturing sites certified in 2016)
- The ISO 9001 quality management certification.

#### Circular economy

In 2016, the promoter developed and deployed a new internal KPI: Circular Revenues. The Circular Revenues percentage captures the revenues of validated circular products, as a % of total Philips revenues. The validation is done against the following circularity requirements: 1) Performance and access-based models, 2) Refurbished, reconditioned and remanufactured products/systems, 3) Refurbished, reconditioned and remanufactured components, 4) Upgrades/refurbishment on site or remote, 5) Products with recycled plastic content. The promoter has set a target to reach 15% of revenues from circular proposition by 2020 (7% in 2015 and 9% in 2016).

#### Animal testing

Philips has a strict Animal testing policy, according to which it does not test products on animals unless necessary to demonstrate product safety, effectiveness, ability to function with living tissue without harming tissue (biocompatibility), or required by law and/or regulations.

Philips is committed to prevent animal testing as much as possible by pro-actively choosing design, development and manufacturing solutions that do not require biocompatibility testing and are acceptable to regulatory authorities. Animal testing is however required in some circumstances where medical products feature novel technologies or new materials that do not have scientific information available on biological interaction in order to meet regulatory requirements. Even in these cases, Philips is committed to utilising accepted, alternative test methods and raw materials with well-established safety records whenever permissible to reduce and potentially eliminate the need for animal testing. Any studies involving animals should be performed in accordance with applicable standards, regulations, and laws. In case animal testing is performed, Philips follows all required standards and processes to ensure that evidence is documented that such testing is necessary and that all applicable laws and/or regulations were followed during testing. Philips uses test facilities that follow relevant/appropriate Good Laboratory Practice standards and national law.

## **Conclusions and Recommendations**

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required by EIA Directive 2011/92/EU as amended. The Promoter has an integrated environmental and quality management system and effective operating procedures in place which are in line with best industry standards.

Considering the above, the project is acceptable for Bank financing.