

Environmental and Social Data Sheet

Overview

Project Name: LIVANOVA R&D
Project Number: 2016-0607
Country: Italy and France
Project Description: Financing of the LivaNova Group research and development activities in the cardiac surgery and cardiac rhythm management.

EIA required: no

Project included in Carbon Footprint Exercise¹: no

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 Italy (Mirandola and Saluggia) and France (Clamart).

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

- The QSR under section 520 of the US FDCA and its implementing regulations at 21 C.F.R. Part 820;
- The International Standards Organisation – EN ISO 13485:2012, Medical devices – Quality management systems;
- The independent certification bodies – DEKRA, LNE/G-MED and TUV SUD act as LivaNova's notified bodies 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.

¹ 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, 04.04.2017

In addition, LivaNova 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 Italian regulations under the Integrated Environmental Authorisation acts;
- The ISO 14001 environment management certification.

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. 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.