Luxembourg, 13 March 2014

Environmental and Social Data Sheet

Overview

Project Name:	**GRUPPO SORIN R&D**
Project Number:	**2013-0335**
Country:	Italy and France
Project Description:	Financing of the Sorin Group research and development activities in the cardiac surgery and rhythm management fields.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

Summary of Environmental and Social Assessment, including key issues and overall conclusion and recommendation

Research and development activities on medical devices are not specifically mentioned under the EIA Directive. The project's activities 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 project per se does not have any impact on the environment; however the new medical devices resulting of the project will be more efficient and safer, including implantable devices that will be easier to implant and therefore reduce the risks and duration of surgical interventions. More generally, the new products will also contribute to improve the patients' quality of life. The project can therefore be classified as "acceptable with positive impacts".

Environmental and Social Assessment

Environmental Assessment

The project will be managed and carried out by the promoter's existing R&D staff mainly located at the promoter's existing R&D centres in Italy (Mirandola and Saluggia) and in France (Clamart and Meylan). 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 operating procedures in place are in line with the sector standards.

Social Assessment

The clinical trials which are included in the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMA in Europe and/or national equivalent bodies in the rest of the World (FDA, PMDA, SFDA, etc.).

Other Environmental and Social Aspects

The promoter uses animals for research, safety testing of products where no acceptable alternative methods exist, as animal testing are necessary at pre-clinical stage. Still, the promoter is committed to apply the "3R" principle that consists in Replacing animal use by alternative methods when possible, Reducing the number of animals used as much as possible and Refining the testing methods to reduce animals' pain and distress.

[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.