



Luxembourg, 25th July 2024

Public

Environmental and Social Data Sheet¹

Overview

Project Name:	PROTEMBO (IEU LS)
Project Number:	2023-0808
Country:	Germany
Project Description:	Quasi-equity financing to a German medtech company developing a best-in-class catheter-based filter device to protect patients from strokes and silent infarcts during cardiovascular interventions, such as transcatheter aortic valve implantation (TAVI).
EIA required:	no
Invest EU sustainability proofing required	yes
Project included in Carbon Footprint Exercise ² :	no

Environmental and Social Assessment

Environmental Assessment

The Promoter is a medical technology company focused on the development and commercialisation of cerebral protection devices for applications during transcatheter aortic valve implantations (TAVI).

The project concerns investments in research and development activities, carried out by the Promoter and its partners in existing facilities without changing their already authorised scope. The project is neither listed under Annex I nor Annex II of the EIA Directive 2011/92/EU amended by Directive 2014/52/EU, so the project is not subject to an EIA procedure.

¹ The information contained in the document reflects the requirement related to the environmental, social and climate information to be provided to Investment Committee as required by the Invest EU Regulation and it represents the equivalent of the information required in the template of the InvestEU sustainability proofing summary

² Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO₂e/year absolute (gross) or 20,000 tonnes CO₂e/year relative (net) – both increases and savings.



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Climate Assessment

Research and development activities, such as those present in this project, neither present significant negative nor positive impacts for climate aspects.

The project has been assessed for Paris alignment and is considered to be aligned with the Paris Agreement, as defined in the EIB Climate Bank Roadmap.

The Promoter is in scope but screened out of the PATH framework as it does not operate in a high emitting sector and is not considered as a highly vulnerable counterpart.

Social Assessment

The Project does not have significant negative social impacts, as the Promoter is expected to carry out its activities in compliance with applicable local labour and social standards.

For pre-clinical and clinical trials, the Promoter retains the services of subcontractors (such as Clinical Research Organisations) and relies on their official policies, processes, and qualifications, considering the high level of scrutiny and responsibility involved in such operations.

Other Environmental and Social Aspects

The Promoter follows the relevant guidelines for medical devices of the European Commission MEDDEV 2.7/1 (rev. 4) of June 2016 and the Medical Device Regulation (EU) 2017/745 (MDR). It is certified as a medical technology manufacturer in compliance with the international standard ISO 13485:2016. Clinical studies are conducted in accordance with DIN EN ISO 14155:2018 and GCP (Good Clinical Practice, Directive 2001/20/EC) and relevant US Federal Drug Administration (FDA) regulations.

If successful, the project is expected to lead to important social benefits, considering the targeted indications and the level of unmet medical need. Through the R&D activities and investments, the Promoter is also expected to sustain its current level of skilled personnel, while contributing to European scientific innovation, hence fostering and nurturing the vital research community.

Conclusions and Recommendations

The project's activities are not specifically listed in EIA Directive 2011/92/EU amended by Directive 2014/52/EU, thus it is not subject to an EIA procedure. The research activities will be executed in existing and already authorised research facilities, expected to be in compliance with applicable national and EU environmental legislation.

The project is not expected to generate significant negative environmental or social impacts.

Sustainability proofing conclusion: The Project is carried out in compliance with applicable national and EU environmental and social legislation. Based on the environmental, climate and social information and based on the review of the likely significant environmental, climate and social risks and impacts and the mitigation measures and management systems in place, the Project is deemed to have low residual environmental, climate and social risks and impacts. No further sustainability proofing is therefore required.

Considering the above, the project is considered acceptable for Bank financing in environmental and social terms.