

Luxembourg, 17 June 2025

Public

Environmental and Social Data Sheet¹

Overview

Project Name:	PRECISIS RDI (IEU TI)
Project Number:	20240411
Country:	GERMANY
Project Description:	The project supports research, development and clinical evaluation of an implantable brain pacemaker used as a treatment to decrease seizures in patients with focal epilepsies.

EIA required:	no
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Invest EU sustainability proofing required	yes
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Project included in Carbon Footprint Exercise ² :	no
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Environmental and Social Assessment

Environmental Assessment

The Promoter is a medical technology company and develops transcranial focal cortex stimulation devices for patients with focal epilepsy that do not respond to medical therapy.

The project concerns investments in research and development activities, to be carried out by the Promoter and its partners in existing facilities which do not require changing their already authorised scope. The project is not listed under Annex I nor Annex II of the EU EIA Directive 2011/52/EU amended by Directive 2014/52/EU, therefore it is not subject to an EIA procedure.

Climate Assessment

Research and development investment activities, such as those present in this project, are regarded presenting a neutral climate impact.

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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The project has been assessed for Paris alignment, it 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 likely significant negative social impacts, the Promoter in fact 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.

In alignment with these rigorous standards, pre-clinical activities comply with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable. Likewise, clinical trials are conducted in compliance with Regulation (EU) No. 536/2014, where applicable, and the Promoter adheres to all legal standards for anonymisation and data protection.

Other Environmental and Social Aspects

The Promoter is ISO 13485 certified and maintains a quality management system (QMS) that meets or exceeds the requirements of the EN ISO 13485 standard.

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 listed by EIA Directive 2011/92/EU amended by Directive 2014/52/EU, therefore the project 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 all applicable 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 review of environmental, climate and social information and associated likely risks, impacts, 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.