



Luxembourg, 19 July 2023

Public

Environmental and Social Data Sheet¹

Overview

Project Name:	SAFEHEAL (IEU TI)
Project Number:	2022-0828
Country:	France
Project Description:	Development of innovative solutions to prevent anastomotic leakage following colorectal surgery
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 medtech company focused on development and commercialization of a cutting-edge device within medical technology. The Promoter is developing a device addressing colorectal surgery complications, with potential scale-up application.

The costs are mostly covering OPEX (e.g. pre-clinical and clinical trials, R&D personnel, regulatory, IP) and CAPEX (new and specialised equipment) to perform research and development activities.

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 research and development activities of the project do not fall under neither Annex I or Annex II of the EU Directive 2014/52/EU amending 2011/92/EU.

Climate Assessment

The project has been assessed for Paris alignment and is considered to be aligned both against low carbon and resilience goals against the policies set out in the Climate Bank Roadmap and/or associated guidance and other relevant documents (e.g. the ELP). As the treatment would be more accurate and effective, while encompassing fewer hospital visits, it would have lower derived environmental impacts than existing standard of care and related therapies.

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 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.

Other Environmental and Social Aspects

If successful, the project will contribute to the creation and deployment of a superior solution which would prevent anastomotic leakage after colorectal surgery and postoperative recovery. As such, this project will improve treatment options for patients, in turn contributing positively to quality of life as well as overall survival.

Through the R&D activities and investments, the project will aid the Promoter to create additional highly skilled RDI jobs, while positively contributing to European scientific innovation, hence fostering and nurturing the vital research community.

The health and safety arrangements for the staff, especially those working with biological hazards, comply with the relevant EU directives and guidelines for workplaces, equipment, signs, personal protective equipment and exposure to biological agents at work according to the EU guidelines, and other relevant regulations.

Conclusions and Recommendations

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

Considering the above, taking into consideration the Environmental, Social and Climate impacts of this RDI project, including the capacity of the promoter and the overall net positive social impact, this project is deemed acceptable for the Bank's financing under environmental and social terms.