European Investment Bank

Luxembourg, 27 April 2026

Environmental and Social Data Sheet[1]

Overview

Project Name:	TECHEU VD TENSIVE (BIOTECH ACT)
Project Number:	2026-0015
Country:	Italy
Project Description:	The Project concerns the Promoter's research and development activities and CAPEX expenditures to advance regenerative implants for reconstructive surgery and for tissue marking following lumpectomy or mastectomy in breast cancer patients.

Invest EU sustainability proofing required	yes
E&S Risk categorisation	Low as per paragraph 4.18 of E&S Policy
Project included in Carbon Footprint Exercise[2]:	no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

Environmental and Social Assessment

Environmental Assessment

The Promoter is a clinical-stage medical device company specialised in the development of bioresorbable scaffold technologies for soft-tissue regeneration, with a primary focus on breast-conserving cancer surgery and tumour bed marking.

The Project mainly concerns research, clinical development, regulatory activities and early industrialisation related to the Promoter's medical device platform for soft-tissue regeneration. Project activities are expected to be carried out by the Promoter and its partners within existing facilities. The Project may also support investments related to the equipment, validation and scale-up of laboratory and manufacturing facilities. These activities are not expected to fall under Annexes I or II of the EU Directive 2011/92/EU as amended by the 2014/52/EU Directive, therefore an EIA is not required.

The Promoter will verify the specific regulatory requirements, and, when needed, carry out the procedures to obtain the necessary permits and authorisations by the competent authorities, in

[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.

compliance with applicable national legislation and EU Directive 2011/92/EU as amended by the 2014/52/EU Directive.

Climate Assessment

The Project has been assessed for Paris alignment and is considered aligned with the EIB's climate mitigation and adaptation objectives, in line with the Climate Bank Roadmap (Annex 2, Industries, RDI) and associated guidance. The Project mainly consists of research, clinical development, regulatory activities and early industrialisation in the medical device sector and does not involve carbon-intensive activities or result in material greenhouse gas emissions. On this basis, the Project is considered Paris-aligned.

EIB Paris Alignment for Counterparties (PATH) Framework

The Promoter is in scope of the PATH framework but screened out, as it does not operate in a high-emitting sector and is not considered to be a highly climate-vulnerable counterparty.

Social Assessment

The Promoter's research and development (R&D), clinical and manufacturing activities are carried out in compliance with applicable national and EU legislation. The Promoter maintains adequate internal policies and management practices with respect to labour standards, occupational health and safety, and working conditions.

If successful, the Project is expected to generate important social benefits by addressing a significant unmet medical need in breast-conserving cancer surgery. As the targeted indications primarily affect women, the Project has the potential to contribute positively to women's health, in particular by improving health outcomes, quality of life and post-treatment recovery for patients undergoing breast cancer treatment.

Other Environmental and Social Aspects

Through the R&D activities and investments, the project will result in the creation of additional highly skilled jobs, while positively contributing to European scientific innovation, hence fostering and nurturing the vital research community.

The Quality Management System (QMS) of the Promoter is based on EN ISO 13485:2016 and has been certified by a relevant Notified Body. The QMS is maintained compliant with medical device related regulations, guidelines, and industry standards.

The Promoter is committed to animal welfare and the responsible use of animals for scientific purposes, ensuring that pre-clinical activities, whether performed directly or by subcontractors, comply with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable.

For 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. 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.

Conclusions and Recommendations

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The Promoter has effective policies and procedures in place, which are in line with industry standards. The project concerns investments in R&D for which no significant impact on the environment is expected.

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 non-significant residual ECS risks and impacts. No further sustainability proofing is required.

Undertakings

The Promoter shall, during the course of the Project implementation, notify the Bank about any subsequent change, modification or extension of the Project that could trigger a permitting process, following EU Directive 2011/92/EU amending 2014/52/EU Directive, and submit the relevant assessment reports and permits to the Bank.

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 in environmental and social terms.