

Luxembourg, 9 December 2024

Public

Environmental and Social Data Sheet¹

Overview

Project Name: NORLASE RDI (IEU LS)

Project Number: 2023-0605 Country: Denmark

Project Description: The project supports the development and market access of

innovative portable ophthalmic lasers to diagnose and treat causes of vision loss and blindness. Key project elements are novel eye laser technologies, including expansion of

production facilities.

EIA required: no

Invest EU sustainability proofing required yes
Project included in Carbon Footprint Exercise²: no

Environmental and Social Assessment

Environmental Assessment

The Promoter is a medical technology company focused on the development and commercialization of next-generation laser solutions for the treatment of retina and glaucoma disease.

The project concerns investments in research and development activities, carried out by the Promoter in existing facilities without changing their already authorised scope. The project is not listed under Annex I nor Annex II of the EIA Directive 2011/92/EU amended by Directive 2014/52/EU.

Climate Assessment

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

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 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.

Other Environmental and Social Aspects

The Promoter follows the relevant guidelines for medical devices of the European Commission and the Medical Device Regulation (EU) 2017/745 (MDR). It is certified as a medical technology manufacturer in compliance with the international standards ISO 13485:2016 and QSR 820 (US/FDA).

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. The research activities will be executed in existing and already authorised research facilities, expected to be in compliance with all applicable EU environmental legislation.

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.