



Luxembourg, 22/12/2022

Environmental and Social Data Sheet

Overview

Project Name:	BRAINLAB SURGERY SOFTWARE DEVELOPMENT
Project Number:	2020-0610
Country:	Germany
Project Description:	The promoter`s R&D activities within software-based technology and hardware medical devices aiming to improve critical surgeries, radiosurgery treatments and operating room efficiency.
EIA required:	no
Project included in Carbon Footprint Exercise ¹ :	no

Environmental and Social Assessment

Environmental Assessment

The specific RDI activities included in the project relate to the development of software and engineering solutions to be performed in existing facilities without changing their already authorised scope. Therefore, the project activities neither fall under Annex I nor Annex II of the EU EIA Directive 2011/52/EU amended by Directive 2014/52/EU.

The medical devices (including hard and software) to be developed as a result of the project are defined as Class II, IIa and IIb Medical Devices. The promoter is in compliance with the regulations set by the EU MDD (Medical Devices Directive) 93/42/EC, as well as by the US FDA and equivalent regulations in all the territories where it operates. The promoter is engaged in an ongoing effort to ensure compliance with the forthcoming EU MDR (Medical Device Regulation).

Other Environmental and Social Aspects

If successful, the project will contribute to the creation and deployment of soft- and hardware-based advances in the field of operating room digitalisation and efficiency, for example by improving the precision in cranial and spinal surgery through the use of big data and AI in robot guided surgery, that way improving clinical outcomes and, in turn, patients' quality of life.

Through the R&D activities and investments, the Promoter is also expected to create highly skilled jobs within R&D and create, enhance and disseminate big data-based knowledge, thus contributing to European scientific innovation, hence fostering and nurturing the vital research community.

Conclusions and Recommendations

Therefore, the project is considered acceptable in environmental and social terms for the Bank's financing.

¹ 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.