

**Public**

## **Environmental and Social Data Sheet**

### **Overview**

Project Name:	SURGIVISIO (EGFF)
Project Number:	2020-0330
Country:	France
Project Description:	Quasi-equity financing of Surgivisio, an innovative medtech company based in France. The project is dedicated to financing the company's RDI and Capex costs for the development of its robotic surgery products.
EIA required:	no
Project included in Carbon Footprint Exercise <sup>1</sup> :	no

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

### **Environmental and Social Assessment**

#### **Environmental Assessment**

The activities to be financed are research, development and innovation in the medical technology sector, enabling the company to develop its robotic surgery products. Due to the project's characteristics, the project does not fall under Annex I or Annex II of the EIA Directive 2014/52/EU amending Directive 2011/92/EU.

The promoter's R&D facilities and practices are in compliance with relevant national and EU regulations. The promoter maintains adequate internal procedures and management practices and its operations are certified under ISO 13485:2016 (Medical devices -- Quality management systems). The clinical trials which are sponsored by the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMA in Europe and/or national equivalent bodies in the rest of the world (e.g. FDA).

The operating procedures in place are in line with best industry standards and are subjected to regular external audits.

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<sup>1</sup> 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.

Luxembourg, 18/12/2020

### **Other Environmental and Social Aspects**

If successful, the project is expected to lead to important social benefits stemming from the development of a surgical robotic system addressing the unmet medical need for an improved, safe and easier way to perform orthopedic and spinal surgery.

Through the R&D activities and investments, the promoter expects to increase its current level of highly skilled personnel, while contributing to European scientific innovation, hence fostering and nurturing the vital research community.

### **Conclusions and Recommendations**

If successful, the project presents potentially high health and public benefits for the wider society. Considering the above, and the promoter being fully compliant with the applicable EU directives, regulations and standards across all business lines and processes, the project is deemed acceptable for the Bank's financing in environmental and social terms.