

**Public**

## Environmental and Social Data Sheet

### Overview

Project Name:	MAUNA KEA TECHNOLOGIES (EGFF)
Project Number:	2018-0349
Country:	France
Project Description:	The Promoter, a medical device Company, develops and sells medical imaging devices for the diagnosis and treatment of cancer and other diseases. The Company has products on the market and operates internationally.
EIA required:	no
Project included in Carbon Footprint Exercise <sup>1</sup> :	no

### Environmental and Social Assessment

#### Environmental Assessment

Mauna Kea designs and develops the advanced probe-based confocal laser endo-microscopy system (pCLE), named Cellvizio. The device permits an in-vivo microscope-like visualization of the mucosa during endoscopy procedures, hence optimizing the medical investigation, while reducing the need of biopsy.

Cellvizio system must satisfy the key requirements of the Directive 93/42/EEC (concerning medical devices) to obtain the CE marking.

The investments to be financed concern research, development and innovation activities that will be in the medical devices sector, enabling the company to work on a second generation of its pCLE device with improved features, while expanding its market.

The project's activities are not listed in any of the annexes of the EU Directive 2011/92/EU (on the assessment of the effects of certain public and private projects on the environment) as amended by 2014/52/EU. Furthermore, the project will be conducted in existing facilities already authorised for similar activities and volumes. Therefore, an Environmental Impact Assessment (EIA) is not required.

In addition, the Company's quality control system has been certified by a third-party organisation in accordance with the regulatory requirements of the applicable European Directive 93/42/EEC and the reference standards on quality management (ISO 9001 and more specifically ISO 13485 for medical devices). CE marking via the declaration of CE compliance is based on a complete audit of the quality assurance system with an assessment of all the Company's processes and focusing on activities linked to the product.

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<sup>1</sup> Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO<sub>2</sub>e/year absolute (gross) or 20,000 tonnes CO<sub>2</sub>e/year relative (net) – both increases and savings.

Luxembourg, 13/06/2019

## **Other Environmental and Social Aspects**

Mauna Kea has an internal safety and environmental health policy, including a commitment to comply with legal requirements, pollution prevention and continual improvements and undertakes regular audits. The project, if successful, is expected to lead to significant social benefits. Evidence based micro-endoscopy diagnostics of early-cancer lesions is demonstrated to be effective in lowering morbidity and mortality as well as cost-effective from an economic point of view.

## **Conclusions and Recommendations**

Overall, the project can be classified as acceptable with no residual impact. If successful, the project presents high potential health and social benefits for society. The project is therefore considered acceptable for EIB financing in environmental and social terms.

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