



Luxembourg, 12.10.2023

Environmental and Social Completion Sheet (ESCS)¹

Overview

Project Name:	VIVASURE (EGFF)
Project Number:	20180548
Country:	Ireland
Project Description:	Financing of Vivasure Medical, an innovative medtech company based in Ireland. The financing will help Vivasure Medical to develop pioneering surgical closure device products for vascular access procedures.

Summary of Environmental and Social Assessment at Completion

EIB notes the following Environmental and Social performance and key outcomes at Project Completion.

The project concerned investments in research and development in the medical technology sector that were carried out in existing facilities without changing their already authorised scope. The project does not fall under the EIA Directive 2014/52/EU amending Directive 2011/92/EU.

The promoter's practices are in compliance with the relevant national and EU legislation (Directive 93/42/EEC concerning medical devices as amended and applicable good practice quality guidelines and regulations). The promoter maintains adequate internal procedures and management practices and is certified under ISO 13485.

The project's R&D activities were a central part of the promoter's operations and were embedded in the existing organisational and management structure. The operating procedures in place were in line with best industry standards and are regularly audited externally.

The research activities undertaken in the project were aimed to result in new and improved medical devices with a positive impact on healthcare quality. Therefore, the project led to positive social impacts.

Summary opinion of Environmental and Social aspects at completion:

EIB is of the opinion based on reports from the promoter that the Project has been implemented in line with EIB Environmental and Social Standards, applicable at the time of appraisal.

¹ The template is for ILs and FLs