



Luxembourg, 18.09.2024

Environmental and Social Completion Sheet (ESCS)

Overview

Project Name:	DEMANT MEDICAL TECHNOLOGY RDI
Project Number:	2022-0389
Country:	Denmark, Poland
Project Description:	Financing the promoter's RDI investments to develop new technology hearing aids.

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 that were carried out in existing facilities in Denmark and Poland, without changing their already authorised scope. The project was not subject to EIA Directive 2014/52/EU amending Directive 2011/92/EU.

The hearing aids developed within the scope of the project are defined as Class IIa Medical Devices. The promoter follows the regulations set by the EU MDR (Medical Devices Regulation, 2017/746), as well as by the US FDA and equivalent regulations in all the territories where it operates.

Demant's hearing healthcare products are developed under a highly regulated quality system complying with ISO 13485 and FDA 21CFR 820 CGMP, as well as other national standards. Furthermore, hearing aids are in principle subject to regulations related to electromagnetic radiation, as some models contain 2.4 GHz radio transceivers. However, the promoter's products operate with low power (around 1 mW) which is significantly below the threshold (20 mW) to require SAR (Specific Absorption Rate) measurements.

The promoter's products and activities (including this project) comply with the EU RoHS2 (Restriction of Hazardous Substances in Electrical and Electronic Equipment) and WEEE (Waste Electrical and Electronic Equipment) Directives, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation as well as other applicable international and local regulations.

The project led to significant social benefits resulting from new and improved hearing aid technologies to alleviate the problems linked to living a life with hearing loss.

The promoter is a signatory of the UN Global Compact and produces an annual Sustainability report (covering all ESGs) to communicate its progress and further aspires to have zero environmental impact by 2050, and in 2021, they committed to the Science Based Targets initiative.

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.