

Public

Environmental and Social Data Sheet

Overview

Project Name:	GN STORE NORD - HEARING AIDS RDI
Project Number:	20200130
Country:	Denmark
Project Description:	RDI investments to develop new hearing devices
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 will not have any relevant environmental impact, as they relate to development of software and engineering solutions to be performed in existing facilities without changing their already authorised scope.

The hearing devices to be developed as a result of the project are defined as Class IIa 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 ongoing effort to ensure compliance with the forthcoming EU MDR (Medical Device Regulation).

GN's hearing 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 devices are in principle subject to regulations related to electromagnetic radiations, 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) measurements². The promoter has all their products tested by an independent accredited test house to formalise their compliance with electromagnetic radiations regulations.

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,

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.

² Based on standard EN 62479:2010: Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz).

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Authorisation and Restriction of Chemicals) Regulation as well as other applicable international and local regulations.

Other Environmental and Social Aspects

The project is expected to lead to significant social benefits resulting from new and improved hearing aid technologies to alleviate the problems linked to a hearing impairment.

The promoter is a signatory of the UN Global Compact since 2010 and produces an annual Corporate Responsibility report to communicate its progress.

Conclusions and Recommendations

The project activities do not fall under Annexes I and II of the EIA Directive 2014/52/EU amending Directive 2011/92/EU, and are therefore not subject to mandatory Environmental Impact Assessments. The proposed investments will take place inside buildings at existing RDI facilities without changing their already authorized scope, and are not expected to have a significant environmental impact on the surroundings. The promoter complies with all relevant regulations and recommendations related to its business.

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