NordicNeuroLab Transparency Statement

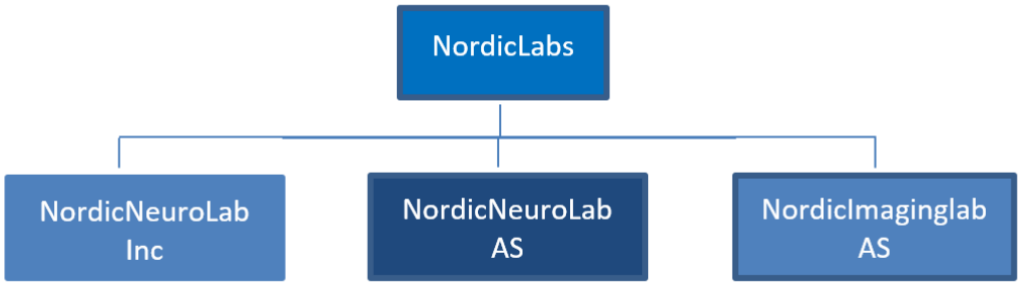
Introduction

The Norwegian transparency act requires Norwegian companies to carry out due diligence activities to ensure they are operating responsibly, respecting both human rights and decent working conditions. NordicNeuroLab fulfill the criteria of the act and this document provides a statement about how the company ensures compliance.

NordicNeuroLab organization

NordicNeuroLab is a manufacturer of medical devices for use in the hostile MR environment. The company focus on three main segments for the MR room; functional MRI, patient comfort and in-room image guidance. Using our high competence, knowledge, and experience with advanced functional MRI applications we shall encourage the use of functional MRI in the clinical workflow enabling physicians and hospitals to improve patient care.

The headquarters with research and development, production, and sales activities are located in Bergen, Norway.



NordicLabs employs administrative resources which are shared among the subsidiary companies.

NordicNeuroLab AS, a subsidiary of NordicLabs, develops software and hardware products for functional MRI. It also manufactures hardware products and sells / markets the company's products worldwide.

NordicNeuroLab Inc., in Milwaukee, Wisconsin, USA acts as a regional sales and service organization covering North, central, and South America.

NordicImagingLab AS, a subsidiary of NordicLabs, and develops post processing software.

Quality System

NordicNeuroLab maintains a documented Quality system to meet the requirements of the:

- ISO 13485:2016 Standard/ NS-EN ISO 13485:2016
- SOR 98/282: Medical Device Regulation (Canada)

- Medical Device Regulation (MDR) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- Quality System Regulations (QSR – 21 CFR 820) of the US FDA
- Therapeutic Goods (Medical Devices) Regulations- Australia
- Standard for Manufacture and Quality Management of Medical Device Ministry of Food and Drug Safety (MFDS) Notification – South Korea
- General Data Protection Regulation (GDPR) - REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016.
- ISO/IEC 27001:2017 Information technology - Security techniques - Information security management systems – Requirements

In addition to complying with the above-described standards and regulations, the company is registered under the MDSAP program, Health Canada - "The registration covers the Quality Management System for design, development, manufacture, sales, installation, and service of MR compatible medical devices and analysis software for use in clinical / research applications".

The company's ESG policy and code of conduct document lays out the guiding principles regarding areas of human rights and decent working conditions.

Supplier selection & re-evaluation

NordicNeuroLab's supply chain is the area of the business where exposure to the risk of potential breaches of human rights and decent working conditions may occur. To ensure responsible sourcing, all suppliers must fulfill strict evaluation criteria according to NL-100-0013, as part of the supplier selection process.

Supplier performance is continuously monitored through processes for incoming inspections, nonconformity handling, supplier re-evaluation and audit. The necessity for initiating a CAPA can result from these findings.

To monitor supplier performance, regular supplier re-evaluation including supplier audits are carried out. Among the supplier audit criteria is a section on occupational health and safety as per the supplier audit checklist template:

Occupational Health & Safety

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
13	Does the health and safety management system address the safety of personnel without comprising the achievement of product quality requirements?					Procedure for training and communication and participation
14	Does the health and safety management system address the requirement for emergency planning?					Emergency preparedness and response plan, monitoring and performance measurements
15	Does the health and safety policy state the organization's health and safety objectives and management's commitment to continual improvement of H&S metrics?					Policies and procedures, health and safety trend charts, accident rate improvement history
16	Are procedures used for the on-going identification of hazards, the assessment of risks, and the implementation of necessary control measures?					Safety committee or group meeting minutes, accident investigation reports, safety audit reports

If a supplier fails to meet NordicNeuroLab's requirements, NordicNeuroLab will first initiate a CAPA (Corrective and Preventive Action) to identify root cause analysis and implement corrective or preventive action to ensure

that non conformity is not repeated. Non conformities related to occupational health and safety aspects will include investigation with the supplier and follow up actions to ensure the supplier meet the requirements.

If this work does not lead to supplier fulfilling requirements, the purchasing shall stop, or orders kept at a minimum, until an alternative supplier has been selected.

Bergen 30.05.2023

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