Medical Devices

Declaration of Conformity

We, NordicNeuroLab AS declare under our sole responsibility that the products described below meet the provisions of the **Medical Device Regulations 2017/745 of 17 May 2017**, for medical device. All supporting documentation is retained under the premises of the manufacturer.

Manufacturer:	NordicNeuroLab AS
Address:	Møllendalsveien 1 N-5009 Bergen Norway
Product:	ResponseGrips
Version:	**4.0**
Single registration number (SRN):	NO-MF-000000555
Basic UDI DI:	7090042054207F
Risk Class:	**Class I**
Compliance:	Device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745 and with the following standards o IEC 60601-1(IEC 60601-1) o IEC 60601-1-2 (IEC 60601-1-2) o NS-EN ISO 14971:2019/A11:2021(ISO 14971:2019) o ISO 10993-1:2018 o NS-EN ISO 13485:2016 (ISO 13485:2016) o RoHS 2002/95/EC
Expiry Date:	Valid for 2 years from date of issue

Thomas Lie Omdahl
Chief Executive Officer
NordicNeuroLab AS

6/2 -2023

Date (Bergen, Norway)

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