NordicNeuroLab AS





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:	VisualSystem HD(VSHD)
Version:	1.2
Single registration number (SRN):	NO-MF-000000555
Basic UDI Device identifier:	7090042052006X
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 NS-EN ISO 10993-1:2020 (ISO 10993-1:2018) o NS-EN ISO 13485:2016 (ISO 13485:2016) o RoHS 2002/95/EC
Expiry Date: Thomas Lie Omdahl Chief Executive Officer	Valid for 2 years from date of issue 6/2-2023 Date (Bergen, Norway)

NL-200-0554-04- EC Declaration_MDR_VSHD 1.2- EN