BRAINLAB

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Digitally signed by Botnaru Andrei
Date: 2023.02.15 10:04:40 EET
Reason: MoldSign Signature
Location: Moldova

EC-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
Medical device	Curve 1.2 Dual Navigation Station
Trade name(s)	Curve Navigation Station
Directives and Regulations	93/42/EEC, MDD EC 1907/2006, REACH EU 2019/1021, POP 2011/65/EU, RoHS 2014/53/EU, RED 2019/19/EU, WEEE
Classification	Class IIb
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body No	0123
GMDN Code	38723; Robotic surgical navigation system
EC Certificate	No. G1 037489 0056 Rev. 00, Valid until 2024-05-26

We, Brainlab AG, declare under our sole responsibility that:

MDD

- the product specified above is a medical device according to Council Directive 93/42/EEC (Medical Device Directive, MDD) Article 1 and meets the provisions of this Directive.
- the medical device complies with the Essential Requirements stated in Annex I of the Council Directive 93/42/EEC.
- the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance) of the Council Directive 93/42/EEC has been followed.

REACH

- the product specified above, including parts, components and packaging fulfill the requirements of the REACH regulation 1907/2006 and do not contain any Substance of Very High Concern (SVHC) on the current candidate list (Article 57) and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w).

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POP

- the product specified above, including parts, components and packaging fulfill the requirements according to the Art 3(1)(a), 3(1)(b) and 5 of the Stockholm Convention (Art. 3(1), 3(2) and 6(1) of regulation EU 2019/1021) and that they contain none of the POP (persistent organic pollutants) substances listed in Annexes A, B and C of the Stockholm Convention (Annexes I, II and III of Regulation (EU) 2019/1021) - apart from the exemptions expressly listed in the Stockholm Convention Annexes (Art. 4 of the Regulation (EU) 2019/1021).

RoHS

- the product specified above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS directive).

RED

- the product specified above is within the scope of Council Directive 2014/53/EU (Radio equipment, RED) Article 1 and meets the provisions of this Directive
- the apparatus complies with the Essential Requirements stated in the Council Directive 2014/53/EU

WEEE

- the product specified above is compliant with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and meets the provisions of this Directive.

This declaration is valid from the date of signature.

Name	Function	Date	Signature
Florian Hoffmann	Vice President R&D	Feb 18, 2021	

TOGETHER WE ARE MAKING MEDICAL TECHNOLOGY AND KNOWLEDGE MORE IMPACTFUL AND ACCESSIBLE TO PHYSICIANS AND THEIR PATIENTS.

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ATTACHMENT TO EC-DECLARATION OF CONFORMITY

CURVE NAVIGATION STATION

STANDARDS

Standard	Title
IEC 63000:2016	Technical Documentation For The Assessment Of Electrical And Electronic Products With Respect To The Restriction Of Hazardous Substances
EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 62366-1:2015	Medical devices – Application of usability engineering to medical devices
EN 60601-1:2006/ A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010 AMD 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019	Medical devices – Application of Risk Management
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN 62304:2006 + Cor.:2008 + A1:2015	Medical device software - Software life-cycle processes
IEC 62353:2014	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment
EN 301 489-1 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17 V3.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

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Standard	Title
EN 300 328 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
EN 301 893 V2.1.1	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)

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CURVE NAVIGATION STATION

DEVICE IDENTIFIER INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481140809	19901B	Curve 1.2 Dual Navigation Station	Curve Navigation Station