BRAINLAB

Brainlab AG
Olof-Palme-Straße 9
81829 Munich • Germany

phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 33

EC-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
Medical device	Cranial/ENT
Trade name(s)	See attachment below
Directives and Regulations	93/42/EEC, MDD EC 1907/2006, REACH EU 2019/1021, POP 2011/65/EU, RoHS 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).

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).

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	Nov 6, 2023	F Hoff

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ATTACHMENT TO EC-DECLARATION OF CONFORMITY

CRANIAL/ENT

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
ISO 14971:2019	Medical devices - Application of Risk Management
IEC 62366-1:2015 + AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
IEC 62304:2015	Medical device software - Software life-cycle processes
ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
IEC 60601-1:2005 + AMD1:2012 + AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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Standard	Title
IEC 60601-1-2:2014 + AMD1:2020	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 + AMD1:2013 + AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60825-1:2014	Safety of laser products - Part 1: Equipment classification and requirements
EN 62471:2008	Photobiological safety of lamps and lamp systems
ISO 5832-1:2016	Implants for surgery — Metallic materials — Part 1: Wrought stainless steel
ASTM F 2503-13:2013	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO 17664:2017	Sterilization of medical devices - Information to be provided by the manufacturer for the reprocessing of resterilizable devices
ISO 16061:2021	Instrumentation for use in association with non-active surgical implants — General requirements
ISO 7153-1:2016	Surgical Instruments – Materials – Part 1: Metals
AIM 7351731, Rev. 03:2021	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radiation Frequency Identification Readers

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ATTACHMENT TO EC-DECLARATION OF CONFORMITY

CRANIAL/ENT

DEVICE IDENTIFIER INCLUDED

UDI-DI	Article Number	Name, Version
04056481132439	N/A	Cranial 3.1
04056481132439	N/A	ENT 3.1
04056481004798	18370-10	Z-Touch Rev. 2
04056481004781	18390-10A	Softouch Pointer (Rev 3)
04056481004774	18390-40A	Softouch Pointer (Rev 3) Gauge
4056481004569	19148-01A	Calibration Phantom iCT
04056481004637	19142-06	DrapeLink Interface ICT Calib Phantom
04056481114053	19144A	Adhesive Flat Markers for Scanner (10 Pcs)
04056481006495	19102	Registration Matrix iMRI Noras Headholder
04056481131920	19202C	Registration Matrix IMRI GE Headholder
04056481000967	55950-70G	VarioGuide Hardware (Version G)
04056481001001	55950-40B	VarioGuide Array
04056481006051	52003	V-Inset Mayfield Kit
04056481006044	52005	V-Inset IMRIS Kit
04056481006037	52006	V-Inset GE Headholder Kit
04056481002725	41874B	Instrument Calibration Matrix (Rev. 4)
04056481006242	41798	Instrument Adapter Array (Starlink), Size M
04056481006235	41799	Instrument Adapter Array (Starlink), Size M/L
04056481006228	41801	Instrument Adapter Array (Starlink), Size L
04056481006211	41802	Instrument Adapter Array (Starlink), Size XL
04056481005351	55101	Instrument Adapter Clamp (Starlink), Size S
04056481005344	55102	Instrument Adapter Clamp (Starlink), Size M
04056481005337	55103	Instrument Adapter Clamp (Starlink), Size L
04056481005320	55104	Instrument Adapter Clamp (Starlink), Size XL
04056481005313	55105	Adapter for Rectangular Instruments

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UDI-DI	Article Number	Name, Version
04056481005306	55110	Adapter for Cylindrical Instruments
04056481141202	55113	Instrument Adapter Clamp Size L (Softgrip)
04056481141219	55114	Instrument Adapter Clamp Size XL (Softgrip)
04056481005375	55013	Instrument Adapter Offset Link (45° 20mm Starlink)
04056481142209	55016	Instrument Adapter Extension 50mm
04056481141899	41767-19A	Microscope Universal Tracking Array
04056481003777	41767-55B	Microscope Adapter Zeiss
04056481003739	41767-70C	Microscope Adapter Leica
04056481003715	41767-85	Microscope Adapter HS/Moeller
04056481003593	41780-5G	Pointer Blunt Tip
04056481100247	41780-10A	Gauge Brainlab Pointer Sharp Tip
04056481001315	55791A	Multiple Tip Pointer Shaft Starlink
04056481001391	55791-01	Pointer Tip (Offset 0°, length 150 mm)
04056481001377	55791-03	Pointer Tip (Offset 30°, length 95 mm)
04056481001360	55791-04	Pointer Tip (Offset 0°, length 100 mm)
04056481001353	55791-05	Pointer Tip (Offset 0°, length 60 mm)
04056481001346	55791-06	Eraser Pointer Tip (Curved)
04056481001339	55791-07	Eraser Pointer Tip (Straight)
04056481001322	55791-34	Pointer tip straight blunt (d3.4mm)
04056481006303	41725	Standard Cranial Reference Array – 4 Marker
04056481006297	41734	Reference Clamp Universal
04056481002503	52001F	Vario Reference Arm
04056481002701	41877A	Headband Reference Star
04056481138523	41878E	Reference Headband (10 Pcs)
04056481002718	41877-10	Headband Reference Star - Connector
04056481004545	19152-02	Cranial Reference Array Drapelink
04056481004552	19152-01	Interconnector Drapelink
04056481004538	19153-01	Adapter for Mayfield Skull Clamp
04056481004521	19153-02	Adapter for Doro Skull Clamp
04056481004514	19153-03	Base Long for Drapelink
04056481004507	19153-04	Base Short for Drapelink
04056481002459	52129B	Skull Reference Array (Base)

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UDI-DI	Article Number	Name, Version
04056481002473	52122A	Skull Reference Array (Star)
04056481001551	55790-05A	Suction STD (CH8) Starlink
04056481001537	55790-15	Suction FS L (CH8) Starlink Frazier
04056481001513	55790-25	Suction FS R (CH8) Starlink Frazier
04056481001469	55790-50A	Suction MS (CH8) Starlink
04056481001452	55790-55	Suction MS (CH8) Starlink Frazier
04056481001438	55790-65	Suction MS (CH10) Starlink Frazier
04056481001421	55790-70	Suction STD (CH10) Starlink Frazier
04056481001414	55790-75	Suction STD (CH8) Starlink Frazier
04056481001407	55790A	Suction STD (CH10) Starlink
04056481006334	22595	Ultrasound Navigation Adapter Array (Drapelink)
04056481006327	22630	Ultrasound Registration Phantom
04056481002893	41860-35B	Ultrasound Navigation Adapter Base (BK 8862/8863 / N11C5s)
04056481002855	41860-40	Ultrasound Navigation Adapter Base (BK N13C5)
04056481141387	41860-42	Generic Ultrasound Adapter
04056481140854	41860-43	Ultrasound Navigation Adapter Base (BK X18L5s)
04056481002831	41860-5D	Ultrasound Navigation Adapter Base for Aloka UST-9120