BRAINLAB

Brainlab AG
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EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device	Automatic Registration 2.6
Trade name(s)	See Annex II
Intended Purpose	The device enables image guided surgery.
Basic UDI-DI	4056481AutomRegPH
Regulation/Directive	EU 2017/745 EU 2021/2226
Risk class	Class IIb
Rule according to Annex VIII	Rule 11, indent 2
Standards/common specification	See Annex I
Product codes	MDA 0315 Software MDS 1009 Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices MDT 2011 Devices which require packaging, including labelling MDT 2012 Devices which require installation, refurbishment
GMDN code	62783 - Electromagnetic/optical surgical navigation device tracking system
EMDN code	Z12011482 - SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body Identification number	0123
EU Certificate	G10 037489 0059, valid until 2025-09-13

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

MDR

- the device specified above is a medical device according to Regulation 2017/745 Article 2 and meets the provisions of this regulation.
- the device complies with the General Safety and Performance Requirements stated in Annex I of Regulation 2017/745.
- the procedure referred to in Annex IX of Regulation 2017/745 has been followed.

EU 2021/2226

- the device specified above is within the scope of Regulation 2021/2226 on electronic information for use and meets the provisions of this Regulation

This declaration is signed in Munich and valid from the date of signature.

Name	Function	Date, Signature
Martin Immerz	Vice President R&D	22. Sept. 2023

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ANNEX I

AUTOMATIC REGISTRATION

STANDARDS / COMMON SPECIFICATIONS

Standard	Title
EN ISO 13485:2016 + AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015 +AMD1 2020	Medical devices – Application of usability engineering to medical devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
IEC 62304:2006 + AMD1:2015	Medical device software - Software life-cycle processes
MDCG 2018-5	UDI Assignment to Medical Device Software
MDCG 2019-16	Guidance on cybersecurity for medical devices
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
DICOM	Digital Imaging and Communications in Medicine (DICOM)

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ANNEX II

Automatic Registration

DEVICE IDENTIFIERS INCLUDED

UDI-DI	Name, Version	Tradename(s)
04056481145101	Automatic Registration 2.6	• AUTO-REGISTRATION SOFTWARE AIRO SPINE • AUTO-REGISTRATION SOFTWARE AIRO CRANIAL • AUTO-REGISTRATION SOFTWARE AIRO CMF • AUTO-REGISTRATION SOFTWARE LOOP-X SPINE • AUTO-REGISTRATION SOFTWARE LOOP-X CRANIAL • AUTO-REGISTRATION SOFTWARE LOOP-X CMF • AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR SPINE • AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR CRANIAL • AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR CMF • AUTO-REGISTRATION SOFTWARE UNIVERSAL AIR SPINE FOR ONE MOBILE 3D C-ARM • LOOP-X AUTO-REGISTRATION SOFTWARE SPINE 2D-UPDATE