BRAINLAB

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

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

EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device	Brainlab Elements Image Fusion 4.5
Trade name(s)	See Annex II
Intended Purpose	The software uses digital bioimaging to support treatment planning.
Basic UDI-DI	4056481FusionP4
Regulation/Directive	EU 2017/745 EU 2021/2226
Risk class	Class IIb
Rule according to Annex VIII	Rule 11, indent III
Standards/common specification	See Annex I
Product codes	MDA 0315 (Software), MDT 2012 (Devices which require installation, refurbishment)
GMDN code	40885 (Stereotactic system application software)
EMDN code	Z11069082 (Various digital bioimaging management 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

BRAINLAB

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
Claus Promberger	Vice President R&D	Apr 27, 2023

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

BRAINLAB

ANNEX I

BRAINLAB ELEMENTS IMAGE FUSION 4.5

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
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	Medical devices – Application of usability engineering to medical devices
IEC 62304:2006 + AMD1:2015	Medical device software - Software life-cycle processes
IEC 82304-1:2016	Active Health software – Part 1: General requirements for product safety
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
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities

BRAINLAB

ANNEX II

BRAINLAB ELEMENTS IMAGE FUSION 4.5

DEVICE IDENTIFIERS INCLUDED

UDI-DI	Name, Version	Tradename(s)
04056481143992	Brainlab Elements Image Fusion, 4.5	Elements Image Fusion [Ultrasound] Elements Distortion Correction Cranial Elements Curvature Correction Spine Elements Contrast Clearance Analysis Elements Virtual iMRI Cranial