

EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device group	C-arm Adapter + C-Arm Reference
Trade name(s)	see Annex II
Intended Purpose	The C-arm Adapters and C-arm References are accessories to compatible Brainlab image guided surgery applications and are intended enable the registration of image data intraoperatively acquired by compatible C-arms.
Basic UDI-DI	4056481AdapRefJW
Regulation/Directive	EU 2017/745 EU 207/2012 EC 1907/2006, REACH EU 2019/1021, POP
Risk class	Class I
Rule according to Annex VIII	Rule 1, no indent
Standards/common specification	See Annex I
Product codes	MDN1208, MDT2001, MDT2002, MDT2011, MDT2012
GMDN code	62783
EMDN code	Z12130480

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 IV of Regulation 2017/745 has been followed.

EU 207/2012

- the device specified above is within the scope of Regulation 207/2012 on electronic information for use and meets the provisions of this Regulation

REACH

- the device specified above, including parts, components and packaging fulfills the requirements of the REACH regulation 1907/2006.

POP

- the device specified above, including parts, components and packaging fulfills 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 contains 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).

This declaration is valid from the date of signature.

Florian Hoffmann Vice President R&D Munich

Name	Function	Place	Date, Signature
			Feb 20, 2023 

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

ANNEX I

C-ARM ADAPTER + C-ARM REFERENCE

STANDARDS / COMMON SPECIFICATIONS

Standard	Titel
IEC 63000 2016 AMD1 2022	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 14971 2019	Medical devices - Application of risk management to medical devices
ISO 15223-1:2016	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
EN ISO 17664-1 2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
MDCG 2020-5	Guidance on clinical evaluation – Equivalence

ANNEX II

C-ARM ADAPTER + C-ARM REFERENCE

DEVICE IDENTIFIERS INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481113957	19154-01	C-ARM REFERENCE UNIT RIGHT	C-ARM REFERENCE UNIT RIGHT
04056481113940	19154-02	C-ARM REFERENCE UNIT LEFT	C-ARM REFERENCE UNIT LEFT
04056481113933	19154-03	C-ARM ADAPTER ZIEHM RFD 3D RIGHT	C-ARM ADAPTER FOR ZIEHM RFD 3D RIGHT
04056481113926	19154-04	C-ARM ADAPTER ZIEHM RFD 3D LEFT	C-ARM ADAPTER FOR ZIEHM RFD 3D LEFT
04056481140342	19154-05	C-ARM ADAPTER SIEMENS CIOS SPIN LEFT	C-ARM ADAPTER FOR SIEMENS CIOS SPIN LEFT
04056481140359	19154-06	C-ARM ADAPTER SIEMENS CIOS SPIN RIGHT	C-ARM ADAPTER FOR SIEMENS CIOS SPIN RIGHT
04056481143930	19154-07	C-ARM ADAPTER GE OEC 3D LEFT	C-ARM ADAPTER FOR GE OEC 3D LEFT
04056481143947	19154-08	C-ARM ADAPTER GE OEC 3D RIGHT	C-ARM ADAPTER FOR GE OEC 3D RIGHT