

## EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device	Sterilization Tray
Trade name(s)	See Annex II
Intended Purpose	The device is an accessory to compatible Brainlab Instruments and 3rd party instruments intended to serve as containment device before, during and after sterilization for organization, identification, storage and transportation of medical devices that require sterilization prior to use.
Basic UDI-DI	4056481SteriTrayRF
Regulation/Directive	EU 2017/745 EC 1907/2006, REACH EU 2019/1021, POP
Risk class	Class I
Rule according to Annex VIII	Rule 1
Standards/common specification	See Annex I
Product codes	MDN 1208, MDT 2001, MDT 2002, MDT 2011
GMDN code	13730
EMDN code	Z12011380

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 II and III of Regulation 2017/745 has been followed.


**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 signed in Munich and valid from the date of signature.

Florian Hoffmann	Vice President R&D	
_____ Name	_____ Function	Oct. 18, 2022 _____ Date, Signature

# ANNEX I

## STERILIZATION TRAY

### STANDARDS / COMMON SPECIFICATIONS

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 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	Medical devices – Part 1: 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 – Part 1: Critical and semi-critical 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
EN ISO 13732-1:2008	Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces
DIN 58952-2: 2012	Sterilization – Transport baskets for sterile barrier systems – Part 2: Sterilizing baskets made of metal
DIN 58952-3: 2012	Sterilization – Transport baskets for sterile barrier systems – Part 3: Instrument trays for sterilizing goods made of metal
AAMI ST77 2013 (R):2018	Containment devices for reusable medical device sterilization
ANSI/ AAMI ST81: 2004 (R) 2010	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

## ANNEX II

### STERILIZATION TRAY

#### DEVICE IDENTIFIERS INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481122898	52301	STERILIZATION TRAY REGISTRATION 2D C-ARM	STERI TRAY REGISTRATION 2D C-ARM
04056481143602	52303A	STERILIZATION TRAY VARIOGUIDE® ALIGNMENT SYSTEM	STERI TRAY VARIOGUIDE® ALIGNMENT SYSTEM
04056481144678	52303B	STERILIZATION TRAY VARIOGUIDE® ALIGNMENT SYSTEM	STERI TRAY VARIOGUIDE® ALIGNMENT SYSTEM
04056481122850	52305	STERILIZATION TRAY ACCESSORIES CRANIAL (2 OF 2)	STERI TRAY ACCESSORIES CRANIAL (2 OF 2)
04056481139117	52306B	STERILIZATION TRAY ACCESSORIES SPINE	STERI TRAY ACCESSORIES SPINE
04056481122836	52307	STERILIZATION TRAY INSTRUMENTS SPINE	STERI TRAY INSTRUMENTS SPINE
04056481122829	52308	STERILIZATION TRAY INSTRUMENTS TRAUMA	STERI TRAY INSTRUMENTS TRAUMA
04056481122799	52311	STERILIZATION TRAY ACCESSORIES ENT/CMF	STERI TRAY ACCESSORIES ENT/CMF
04056481095390	52313A	STERILIZATION TRAY ACCESSORIES SPINE MIS	STERI TRAY ACCESSORIES SPINE MIS
04056481143282	52315A	STERILIZATION TRAY ACCESSORIES CRANIAL (1 OF 2)	STERI TRAY ACCESSORIES CRANIAL (1 OF 2)
04056481122737	52317	STERILIZATION TRAY REGISTRATION 3D C-ARM	STERI TRAY REGISTRATION 3D C-ARM
04056481141806	52319	STERILIZATION TRAY DRILL GUIDES 200 MM SPINE	STERI TRAY DRILL GUIDES 200 MM SPINE
04056481139353	52324	STERILIZATION TRAY REGISTRATION UNIVERSAL AIR	STERI TRAY REGISTRATION UNIVERSAL AIR
04056481144661	52325	STERILIZATION TRAY VARIOGUIDE® ALIGNMENT SYSTEM	STERI TRAY VARIOGUIDE® ALIGNMENT SYSTEM

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481139094	52331	STERILIZATION TRAY CIRQ® INSTRUMENT HOLDER SPINE	STERI TRAY CIRQ® INSTRUMENT HOLDER SPINE
04056481141226	52332	STERILIZATION TRAY CIRQ® ROBOTIC ALIGNMENT SPINE	STERI TRAY CIRQ® ROBOTIC ALIGNMENT SPINE
04056481141639	52334	STERILIZATION TRAY CIRQ® ROBOTIC ALIGNMENT BIOPSY	STERI TRAY CIRQ® ROBOTIC ALIGNMENT BIOPSY
04056481144333	52335	STERILIZATION TRAY CIRQ® ROBOTIC ALIGNMENT BIOPSY	STERI TRAY CIRQ® ROBOTIC ALIGNMENT BIOPSY
04056481144340	52336	STERILIZATION TRAY CIRQ® ROBOTIC ALIGNMENT SEEG	STERI TRAY CIRQ® ROBOTIC ALIGNMENT SEEG
04056481004859	18099-07A	STERILIZATION TRAY ACCESSORIES EM (1 OF 2)	STERI TRAY ACCESSORIES EM (1 OF 2)
04056481141172	18099-08B	STERILIZATION TRAY ACCESSORIES EM (2 OF 2)	STERI TRAY ACCESSORIES EM (2 OF 2)
04056481113971	19152-05	STERILIZATION TRAY DRAPELINK CRANIAL	STERI TRAY DRAPELINK CRANIAL