

EC-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
Medical device group	Spine & Trauma 3D
Trade name(s)	
Directives and Regulations	93/42/EEC, MDD
Classification	Class IIb
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body No	0123
GMDN Code	38723
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.

This declaration is valid from the date of signature.

Martin Immerz Vice President R&D Munich, May 15th 2023

Name Function Date Signature



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SPINE & TRAUMA 3D

STANDARDS

Standard	Title
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
IEC 62366-1 2015 +AMD1 2020	Medical devices – Application of usability engineering to medical devices
EN 62304:2006 + Cor.:2008 + A1:2015	Medical device software – Software life cycle processes
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
ISO 5832-1:2007	Implants for surgery – Metallic materials – Part 1: Wrought stainless steel
EN ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
ISO 17664:2017	Sterilization of medical devices – Information to be provided by the manufacturer for the reprocessing of resterilizable 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 17665-1:2006)
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
ISO 10993-18 2020 AMD1 2022	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 7153-1:2016	Surgical Instruments – Materials – Part 1: Metals
EN ISO 17664-1:2021	Sterilization of medical devices – Information to be provided by the manufacturer for the reprocessing of resterilizable devices

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SPINE & TRAUMA 3D

DEVICE IDENTIFIER INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481106591	N/A	Spine & Trauma 3D, 2.6	
04056481005986	52417	Array-Extension-75MM-ASM	
04056481005979	52424	"1-Pin" Wrench, X-Press	
04056481005955	52429	Bone Fixator "2-Pin", X-Press	
04056481139278	55758	Spine Reference Clamp (Carbon)	
04056481002404	52410A	REFERENCE ARRAY T- GEOMETRY X-PRESS	
04056481002398	52411A	Reference Array Y-Geometry, X-Press	
04056481002374	52421B	Bone Fixator "1-Pin", X-Press Size-S	
04056481002350	52422B	Bone Fixator "1-Pin", X-Press Size-M	
04056481002343	52423B	Bone Fixator "1-Pin", X-Press Size-L	
04056481139285	55758-30	2.5mm Hex Screwdriver	
04056481142742	55761-02A	Spine Reference Adapter, Long	
04056481142728	55761A	Spine Reference Array (4- Marker)	
04056481002183	52780-10	GAUGE-POINTER-SHARP-TIP- EXTENDED	
04056481002176	52780A	Pointer Sharp Tip Extended	
04056481005122	55839	Drill Guide Handle 4-Marker	

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481139605	56203	Drill Guide Compact Handle 4 Markers	
04056481003500	41839-20A	DRILL GUIDE TUBE 3.0 X 150 MM	
04056481139568	41839-27A	Drill Guide Tube 2.4 X 150mm	
04056481139520	41839-30B	Drill Guide Tube 3.2mm X150mm	
04056481141530	41839-31	Drill Guide Tube 3.2mm X 200mm	
04056481139551	41839-40A	Drill Guide Tube 4.5mm X 200mm	
04056481003418	41839-50	Drill Guide Depth Control	
04056481139612	41839-51	Drill Guide Depth Control Insertable	
04056481141516	41839-52	Drill Guide Depth Control (200mm)	
04056481139537	41839-60A	Drill Guide Tube 2.6mm X 150mm	
04056481141523	41839-61	Drill Guide Tube 2.6mm X 200mm	
04056481003258	41839A	Drill Guide Handle	
04056481003241	41840B	Adapter for Surgical Motor System	
04056481001292	55830-10B	IGS Handle Softgrip 'Gearshift'	
04056481001278	55830-15A	IGS Handle Softgrip 'Universal'	
04056481001261	55830-20A	IGS Tool Star Unit (Precalibrated)	
04056481001254	55830-25A	IGS Tool Star Unit MLCalibration ICM4	
04056481001247	55830-27	Tool Star Unit (pre-calibrated) 4-Marker	
04056481001230	55830-29	IGS Tool Star Unit Cali L – Calibration ICM4	
04056481001223	55830-30A	IGS Awl 4mm	
04056481001216	55830-35A	IGS Awl 3mm	

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481001209	55830-40	IGS Probe Straight 4.5mm	
04056481001193	55830-43	IGS Probe Straight 3.5mm	
04056481001186	55830-45	IGS Probe Curved 4.5mm	
04056481001179	55830-50	IGS Chisel Long	
04056481001162	55830-55	IGS Chisel Short	
04056481001117	55839-10	Drill Guide Trocar Tube 5mm X 180mm	
04056481001100	55839-20	Trocar Reduction Sleeve 2.0mm	
04056481001094	55839-28	Trocar Reduction Sleeve 2.8mm	
04056481001087	55839-32	Trocar Reduction Sleeve 3.2mm	
04056481001070	55839-40	Drill Guide Tissue Protection Sleeve 10mm	
04056481001063	55839-45	Tissue Protection Sleeve Grip	
04056481001056	55839-50	Trocar Insert 5mm	
04056481139599	55839-62	Trocar Sharp Tip 3.2 mm	
04056481139582	55839-64	Trocar Sharp Tip 2.4 mm	
04056481139575	55839-66	Trocar Sharp Tip 2.6 mm	
04056481141554	55839-72	Trocar Sharp Tip 3.2mm (200mm)	
04056481141547	55839-74	Trocar Sharp Tip 2.6mm (200mm)	
04056481001049	55844A	Pedicle Access Needle Guide Tube 1.8 mm	
04056481005245	55741	Handheld Registration Device Fluoro 2D	
04056481113957	19154-01	DrapeLink C-Arm Right	
04056481113940	19154-02	DrapeLink C-Arm Left	

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481113933	19154-03	DrapeLink Adaptor Ziehm Right	
04056481113926	19154-04	DrapeLink Adaptor Ziehm Left	
04056481140342	19154-05	DrapeLink Adaptor Cios Spin Left	
04056481140359	19154-06	DrapeLink Adaptor Cios Spin Right	
04056481094850	55715-10	Fluoro 3D Kit (For 3D C-arms)	
04056481121921	55775	Reflective Disks for 3D/2D Fluoro Kit (21 Pcs.)	
04056481006310	22785	Calibration Adapter Siemens 3D C-Arm	
04056481001636	55733A	Ziehm FD Frame	
04056481001629	55735A	3D FLUORO REGISTRATION ARRAY (FOR 3D FD C-ARM)	
04056481002725	41874B	Instrument Calibration Matrix (Rev. 4)	
04056481006242	41798	INSTR. ADAPTER ARRAY (STARLINK), SIZE M	
04056481006235	41799	INSTR. ADAPTER ARRAY (STARLINK), SIZE ML	
04056481006228	41801	Instr, Adapter Array (Starlink), Size L	
04056481006211	41802	Instr. Adapter Array (Starlink), Size XL	
04056481005375	55013	INSTR. ADP OFFSET-LINK 45° 20MM STARLINK	
04056481142209	55016	Instrument Adapter Extension, 50mm	
04056481005351	55101	Instr Adapt Clamp (Starlink), Size S	
04056481005344	55102	Instr Adapt Clamp (Starlink), Size M	
04056481005337	55103	Instr Adapt Clamp (Starlink), Size L	
04056481005320	55104	Instr Adapt Clamp (Starlink), Size XL	
04056481005306	55110	ADAPTER FOR CYLINDRICAL INSTRUMENTS	

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481141202	55113	Instr Adapter Clamp Size L (Softgrip)	
04056481141219	55114	INSTR ADAPTER CLAMP SIZE XL (SOFTGRIP)	