

## EC-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
Medical device	Cranial IGS System - Ultrasound Navigation
Trade name(s)	Ultrasound Navigation Software
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

15. May 2023



Name

Function

Date

Signature

# ATTACHMENT TO EC-DECLARATION OF CONFORMITY

## CRANIAL IGS SYSTEM – ULTRASOUND NAVIGATION

### 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 to medical devices
IEC 62366-1:2015 + AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2015	Medical device software – Software life cycle processes
EN 1041:2013	Information supplied by the manufacturer with 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

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EC-DECLARATION OF CONFORMITY  
CRANIAL IGS SYSTEM – ULTRASOUND NAVIGATION**

**DEVICE IDENTIFIER INCLUDED**

UDI-DI	Name, Version
04056481142650	Cranial IGS System - Ultrasound Navigation 1.1