BRAINLAB

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Digitally signed by Botnaru Andrei
Date: 2022.11.10 13:16:05 EET
Reason: MoldSign Signature
Location: Moldova

EC DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
Medical device	Disposable Reflective Marker Spheres
Trade name(s)	Disposable Reflective Marker Spheres
Directives and Regulations	93/42/EEC, MDD EC 1907/2006, REACH EU 2019/1021, POP
Classification	Class Is (sterile)
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body No	0123
GMDN Code	47020
EC certificate	No. G2S 037489 0058 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.

REACH

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

POP

- the product specified above, including parts, components and packaging fulfill 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 that they contain 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.

Name	Function	Date	Signature
Florian Hoffmann	Vice President R&D		Florian Hoffmann I am approving this document Nov 26 2021 20:00 +01:00

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ATTACHMENT TO EC-DECLARATION OF CONFORMITY

DISPOSABLE REFLECTIVE MARKER SPHERES

STANDARDS

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 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 11135:2014 + A1:2019	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging design and validation for terminally sterilized medical devices - Part 1: Determination of a population of microorganisms on products
EN ISO 11607-2:2017	Packaging design and validation for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2019	Sterilization of health care products- Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products- Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

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DISPOSABLE REFLECTIVE MARKER SPHERES

DEVICE IDENTIFIER INCLUDED

UDI-DI	Article Number	Name, Version	Tradename(s)
04056481003654	41773G	Disposable Reflective Marker Spheres (90 Pcs)	Disposable Reflective Marker Spheres
04056481003661	41772G	Disposable Reflective Marker Spheres (3 Pcs)	Disposable Reflective Marker Spheres