EU Declaration of Conformity

Manufacturers Name:	BiopSafe ApS
Manufacturers Address:	Carolinevej 2, 1.tv DK-2900 Hellerup, Denmark Email: info@biopsafe.com
SRN (Single Registration Number):	[Pending Eudamed database]
Authorized Representative Name (if applicable):	N/A – the manufacturers business is located within the EU
Basic UDI-DI:	[TBD – class A product deadline may 26th , 2027]
Name of the Device:	BiopSafe®
Product code:	3178-200/3178-600-xx
Intended purpose	Storage, fixation and transportation of specimens from sampling at a local clinic until histopathological analysis of the biopsy at a central laboratory.
Classification:	Class A
Notified Body information:	N/A - Class A device, self-certified
Conformity assessment route:	BiopSafe ApS uses the following conformity route for the CE-marking of their device according the Regulation (EU) 2017/746: Class A: EU conformity declaration according to Annex II + Annex III

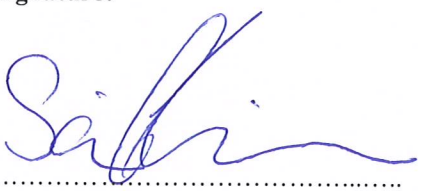
This declaration of conformity is issued under the sole responsibility of BiopSafe ApS. We hereby declare that the device(s) specified above meet the provision of the Regulation (EU) 2017/746 for in vitro diagnostic devices.

All supporting documentation is retained at the premises of BiopSafe ApS.

Place and date of issue:

Vedbæk, 26.05.2022

Signature:



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Søren Christensen
CEO

List of applied standards

Quality management systems

- EN ISO 13485:2016 – Quality management systems

Design and development

- EN ISO 6717:2021 - In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans (pending harmonization for the IVDR)

Risk management

- EN ISO 14971:2019 - Application of risk management to medical devices (pending harmonization for the IVDR)
- EN ISO 23640:2015 - In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (pending harmonization for the IVDR)

Usability

- EN 62366:2015 - Application of usability engineering to medical devices (pending harmonization to the IVDR)

Performance Evaluation

- EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices (pending harmonization for the IVDR)
- ISO 13975:2019 – Plastics, Determination of the ultimate anaerobic biodegradation of plastic materials in controlled slurry digestion systems — Method by measurement of biogas production (pending harmonization for the IVDR)
- EN ISO 10993-1:2020 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-23:2021 - Biological evaluation of medical devices – Part 23: Tests for irritation

Labelling

- EN ISO 18113-1:2011 - In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements (pending harmonization to the IVDR)
- EN ISO 15223-1:2021 - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements