EU Declaration of Conformity

Manufacturers Name:	BiopSafe ApS
Manufacturers Address:	Bygstubben 4 DK-2950 Vedbæk, Denmark Email address: info@biopsafe.com
Authorized Representative Name:	Not Applicable due to location of manufacturing inside the EU.
Name of the Device:	BiopSafe®
Product code:	3178-200-xx size 20 ml., and 3178-600-xx size 60 ml.
Intended purpose:	The BiopSafe® container is intended to preserve tissue in a closed formalin system.
Basic UDI-DI:	05714678
Registration at The Danish Medicines Agency:	33575505
EUDAMED registration:	Not applicable until May 2025 (Pending)
Device Classification:	Medical Device In Vitro Diagnostic, Class A non-sterile.
Conformity assessment route:	The Conformity assessment route for the CE marking of the BiopSafe is according to the Medical Device IVD EU Regulation 2017/746: Classification MD IVD Class A non-sterile: EU Declaration of Conformity according to Annex II + Annex III. Self-certified.
Notified Body information:	Not applicable due to BiopSafe® Classification MD IVD Class A non-sterile.

This EU Declaration of Conformity is issued under the sole responsibility of BiopSafe ApS.

Hereby, BiopSafe ApS declare that the BiopSafe® specified above meets the requirements of Medical Device EU 2017/746 IVD Regulation.

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

Location and date of issue:

Vedbæk, 30. June 2023

Signature:

Mr. Søren Christensen
CEO