EU Declaration of Conformity

Manufacturers Name:	BiopSafe ApS
Manufacturers Address:	Bygstubben 4 DK-2950 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 to 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, 01.10.2022

Signature:

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Søren Christensen
CEO