BiopSafe by Axlab	DOCUMENT ID: BS.20-60.DOC.01	VERSION NUMBER: 01
TITLE:	Declaration of Conformity BiopSafe®Biopsy Container 20 mL and 60 mL	

Identification of the Legal Manufacturer:	BiopSafe ApS Bygstubben 4 DK-2950 Vedbæk, Denmark Email address: info@biopsafe.com CVR. 33575505
Contract Manufacturer Organization (CMO)	SP Medical, Møllevej 1, 4653 Karise
Identification of Authorized Representative:	N/A
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Unique Device Identifier (UDI):	Basic UDI-DI: 5714678BiopSafeNG
Identification of the device(s) concerned:	BiopSafe®Biopsy Container 3178-200-xx size 20 mL 3178-600-xx size 60 mL.
	SRN: DK-IM-000029723
IVT code:	IVT 2002
Intended Purpose:	The BiopSafe® Biopsy Container is intended to preserve tissue in a closed formalin system.
Risk Classification:	Class A as per Annex VIII, Rule 5.
We hereby declare that the above-mentioned devices comply with the In Vitro Diagnostic Medical Devices Regulation EU 2017/746 of the European Parliament and of the Council of 5. April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.	
Applied Main Standards:	EN ISO 13485:2016 + A11:2021* Medical devices. Quality management systems. Requirements for regulatory purposes EN ISO 14971:2019 + A11:2021* Medical devices. Application of risk management to medical devices DS/EN 62366-1:2015 + A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices ISO 6717:2021 In vitro diagnostic medical devices - Single-use containers for the collection of specimens from humans other than blood
Name and address of Notified Body:	N/A
Conformity Assessment Procedure:	Classification MD IVD Class A, non-sterile: EU Declaration of Conformity according to Annex Ii+ Annex III. Self-certified
Applicable CE Certificate(s):	N/A
Registration at the Danish Medicines Agency	33575505
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Søren Christensen Function: CEO Signature:  Title: Søren Christensen, CEO Place of Issue: Vedbæk, Denmark Date: 4/11-2024