Declaration of Conformity

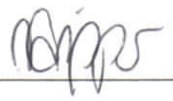
for the

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Histology Wax
Legal Manufacturer: (Name on Label)	POTH HILLE & CO Unit 18 Easter Industrial Park, Ferry Lane South, Rainham, Essex, RM13 9BP, United Kingdom.
SRN:	GB-MF-000010882
Basic UDI-DI:	506002325PHCHWXK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Tissue infiltration and embedding medium.
IVDR Classification:	Class A
Notified Body:	Not applicable for class A devices
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	Conformity assessment as per Article 48.10

Name Matthew Cripps **Position** Technical Director

Signed  **Date** 20/01/2023 **Place** Unit 18 Easter Industrial Park

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 9001:2015	Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to 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
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN code	EMDN code
PHC 5254SF	Histology Wax Low Melt Point	57738	W01030704
PHC 5457SF	Histology Wax Specially Filtered		
PHC 8900	Histology Wax Micro Plus		
PHC 9000	Histology Wax Micro		
PHC 9009	Histology Wax Polymer		
PHC 9010	Histology Wax Polymer DMSO		
PHC 9052	Histology Wax Low Melt Point		
PHC 9056	Histology Wax Specially Filtered		
PHC 9061	High Melt Histology Wax		
PHC 9309	Histology Wax Polymer		
PHC 9310	Histology Wax Polymer DMSO		
PHC 9349	Histology Wax Co-polymer		
PHC 9886	Histology Wax Polymer Blue		

Version History

Version	Compiled by	Date	Description
1.0	Matthew Cripps	01/07/2021	Document created
2.0	Matthew Cripps	30/07/2021	SRN added
3.0	Matthew Cripps	25/08/2021	Basic UDI-DI added
4.0	Matthew Cripps	02/09/2021	GMDN code added
5.0	Matthew Cripps	21/06/2022	Catalogue number PHC 9349 added to appendix II
6.0	Matthew Cripps	06/12/2022	Catalogue numbers PHC 8900, PHC 9309, PHC 9310 added to appendix II
7.0	Matthew Cripps	20/01/2023	EMDN code added