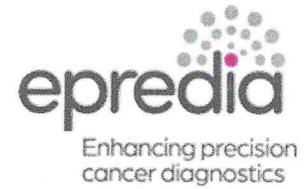


EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



Legal Manufacturer's Name: Shandon Diagnostics Limited, a subsidiary of Epredia
Legal Manufacturer's Address: Tudor Road, Manor Park, Runcorn, Cheshire, WA7 1TA
SRN (Single Registration Number): GB-MF-000008187

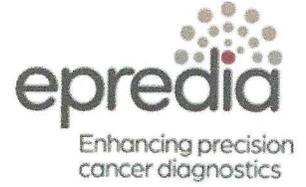
Shandon Diagnostics Limited, a subsidiary of Epredia, declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

Product and Trade Name	Histoplast
Intended Purpose	Histoplast is a mixture of purified paraffin wax formulated for use in routine histological techniques. For use as an infiltration and embedding medium in histology.
Classification & Classification Rules	Class A, Rule 5, Indent (a)
Conformity Assessment Route	In accordance with Article 17 and Annex IV of IVDR 2017/746
Product Number	6774060 - Histoplast 10kg 6774006 - Histoplast 2.5kg
Basic UDI-DI	5051663SDL024KE
Nomenclature	GMDN 57738, Paraffin -based embedding medium IVD
Initial CE Release Date	2007
Authorized Representative Name and Address	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
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EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746



We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746. The devices specified in the product list also conform to the following regulations and directives that provides for the issuing of this EU Declaration of Conformity:

- REACH (1907/2006)

We confirm that the CE-marked IVDs listed in the appendix are manufactured under a controlled and approved Quality Management System that maintains a post market surveillance and vigilance procedure. Each of the listed CE-marked IVD has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the EU IVDR 2017/746 prior to being placed on the market.

Approved by:

Place of Issue: Kalamazoo, US

Mark Ramser
 Vice President, Quality & Regulatory

Date of Issue: 8-August-2022

A handwritten signature in black ink, appearing to read "Mark Ramser", is written over the printed name and title.

Revision: 01

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
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