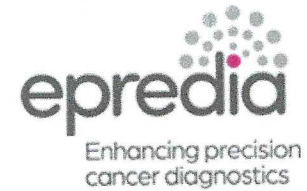


# EU Declaration of Conformity

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.

<b>Product and Trade Name</b>	HistoStar Tissue Embedding System
<b>Intended Purpose</b>	The HistoStar tissue embedding system is an in vitro diagnostic device, intended to be used in laboratories by appropriately trained medical laboratory technicians familiar with tissue embedding techniques and laboratory equipment. The HistoStar is an ergonomically designed, precision engineered, tissue embedding system, comprising two temperature-controlled modules. It is used to embed histologic tissue samples in liquid paraffin wax which when cooled will allow for subsequent tissue processing in preparation for further examination and diagnosis by a technologist or pathologist.
<b>Classification &amp; Classification Rules</b>	Class A, Rule 5, Indent (b)
<b>Conformity Assessment Route</b>	In accordance with Article 17 and Annex IV of IVDR 2017/746
<b>Product Number</b>	As per Appendix 1 (This document) – Device Information
<b>Basic UDI-DI</b>	5051663SDL004K8
<b>Nomenclature</b>	36416 -Tissue embedding unit IVD
<b>Initial CE Release Date</b>	2010
<b>Authorized Representative Name and Address</b>	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
<b>Authorized Representative SRN</b>	NL-AR-000001488

<b>Form Name</b>	EU Declaration of Conformity	<b>Form (Template) Number</b>	GL-FRM-27-0003	<b>Form Template Version</b>	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:

- Machinery Directive (2006/42/EC)
- Low Voltage Directive (2014/35/EU)
- Electromagnetic Compatibility (EMC) Directive (2014/30/EU)
- RoHS Directive (2011/65/EU)
- REACH (1907/2006)
- WEEE (2012/19/EU)
- Battery Directive (2006/66/EC)

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:

Mark Ramser  
 Vice President, Quality & Regulatory

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

Place of Issue: Kalamazoo, US

Date of Issue: 12-May-2022

Revision: 01

<b>Form Name</b>	EU Declaration of Conformity	<b>Form (Template) Number</b>	GL-FRM-27-0003	<b>Form Template Version</b>	2.0
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# EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



• **Appendix 1 – Device Information:**

<b><u>Product Number</u></b>	<b><u>Product Name</u></b>	<b><u>Product Description</u></b>	
A81000001	HistoStar System 220-240V	Tissue Embedding System	
A81000002	HistoStar System 240V	Tissue Embedding System	
A81000003	HistoStar System 100-120V	Tissue Embedding System	
A81000004	HistoStar Cold Mod 220-240V	Cold Module	
A81000005	HistoStar Cold Mod 100-120V	Cold Module	
A81000006	HistoStar Cold Mod 220-240V	Cold Module	
A81000007	HistoStar Embedding Mod	Embedding Module	
A81000008	HistoStar Embedding Mod	Embedding Module	
<b>Associated Accessories:</b>			
A81010030	TAMPING TOOL KIT	A81010036	DOCUMENT HOLDER KIT
A81010031	WAX SCRAPER KIT	A81030197	DISPENSE NOZZLE SHORT
A81010032	MAGNIFIER ASSEMBLY	A81030307	WASTE AREA COVER
A81010033	FORCEPS ELECTRIC RED	AP16125	CABLE
A81010034	FORCEPS ELECTRIC YELLOW	AP16629	SWITCH
A81010035	FORCEPS ELECTRIC BLUE		

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