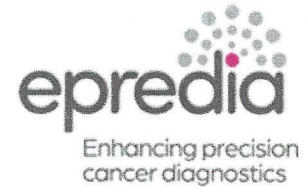


EU Declaration of Conformity

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

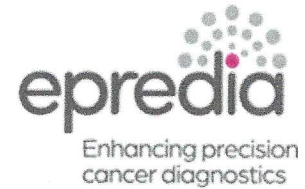
Shandon Diagnostics Limited, a subsidiary of Epredia, declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled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

Product and Trade Name	ClearVue Coverslipper
Intended Purpose	The ClearVue is an in vitro diagnostic device. The automated, high-throughput, precision engineered, slide coverslipper is intended for use in laboratories by trained operatives familiar with coverslipping techniques and laboratory equipment. It is designed to apply a coverslip over a microscope slide to allow for subsequent examination and diagnosis of fixed/stained specimen by a technologist or pathologist.
Classification & Classification Rules	Class A, Rule 5, Indent (b)
Conformity Assessment Route	In accordance with Article 17 and Annex IV of IVDR 2017/746
Product Number	As per Appendix 1 (This document) – Device Information
Basic UDI-DI	5051663SDL010K3
Nomenclature	61826- Microscope Slide Coverslipper, 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

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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:

Place of Issue: Kalamazoo, US

Mark Ramser
Vice President, Quality & Regulatory

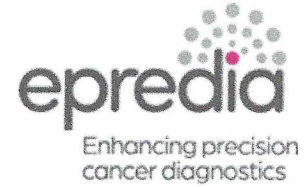
Date of Issue: 27-July 2022

Revision: 02

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



- **Appendix 1 – Device Information:**

<u>Product Number</u>	<u>Product Name</u>	<u>Product Description</u>	
A79200001	ClearVue	Coversipper	
A79200002	ClearVue	Coversipper (China Only)	
Associated Accessories:			
A79210050	SLIP HOPPER 24x40mm #1.5	A79210069	VARISTAIN V24-4 BASKET
A79210051	SLIP HOPPER 24x50mm #1.5	A79210072	LEICA BASKETS (5)
A79210052	SLIP HOPPER 24x55mm #1.5	A79210073	LEICA BASKETS (5)
A79210056	BASKET STAND COMPLETE	A79210092	LOADING TRAY COMPLETE
A79210064	GEMINI BASKETS (5)	A79210099	TRANSFER HEAD - OFFSET
A79210065	GEMINI BASKETS (5)	A79210166	SLIP HOPPER 24x50 #1.0
A79210066	SAKURA DRS2000 BASKET (5)	A79210202	VENT EXTRACTION KIT
A79210067	SAKURA DRS2000 BASKET (5)	P12257	BRUSH FLAT HEAD 25mm
A79210068	SAKURA DRS2000 HANGER (5)	P12940	BRUSH ETERNA PURE BRISTLE

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

Approved Date: 28 Feb 2023

Approval Task Verdict: Approve	Sophie Love, Regulatory Affairs Specialist III (sophie.love@epredia.com) Regulatory Approval 28-Feb-2023 15:35:16 GMT+0000
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QA Approval Task Verdict: Approve	Michael Dodd, (Michael.Dodd@epredia.com) Quality Assurance Approval 28-Feb-2023 15:58:27 GMT+0000
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