EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746

epredia
Enhancing precision cancer diagnostics

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	Gemini AS Automated Stainer
Intended Purpose	The Gemini AS is an in vitro diagnostic device intended to be used by trained medical laboratory technicians. The automated slide stainer is designed for use in histology and cytology laboratories to stain fixed tissue or cell samples on microscope slides, available for subsequent examination and diagnosis 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	5051663SDL007KE
Nomenclature	15599- Microscope slide stainer IVD
Initial CE Release Date	2012
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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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

Place of Issue: Kalamazoo, US

Date of Issue: 12-May-2022

Revision: 01

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

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- **Appendix 1 – Device Information:**

Product Number	Product Name	Product Description	
A81500001	Gemini AS (Heated)	Automated Stainer	
A81500002	Gemini AS (Unheated)	Automated Stainer	
A81500005	Gemini AS (Heated)	Automated Stainer (China Only)	
A81500006	Gemini AS (Unheated)	Automated Stainer (China Only)	
Associated Accessories:			
A78010404	SAKURA CARRIER (PK OF 5)	A78010505	REAGENT POT INSERT
A78010466	BASKET AND CARRIER	A78010510	SLIDE RACK ADAPTOR -
A78010467	VENT ADAPTOR KIT	A79210064	GEMINI BASKETS (5)
A78010487	REAGENT POT (PK OF 3)	A79210065	GEMINI BASKETS (5)
A78010488	MULTI REAGENT POT COVER	A83410036	SLIDE RACK CARRIER
A78010489	SINGLE REAGENT POT COVER	AP14160	INLET HOSE 2.5M LONG