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	Revos Tissue Processor
Intended Purpose	The Revos is an in vitro diagnostic device. The automated tissue processor is intended to be used by trained medical laboratory technicians in a laboratory environment for the rapid and routine fixation, dehydration, clearing and infiltration of pathology specimens to allow 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	5051663SDL001K2
Nomenclature	57859- Tissue Processor IVD, Automated
Initial CE Release Date	2018
Authorized Representative Name and Address	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

Digitally signed by Cernei Silian
Date: 2024.10.02 14:35:26 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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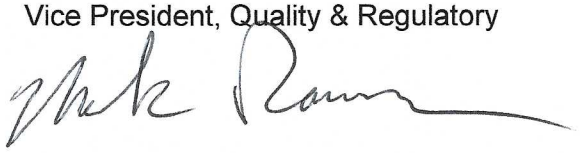
We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746. The devices specified in the product list also conform to the following regulations and directives that provides for the issuing of this EU Declaration of Conformity:

- 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
A84100001	REVOS	TISSUE PROCESSOR
Associated Accessories:		
A78410024	MAIN AIR SYSTEM DUCT ADAPTOR KIT	
A84110031	ORGANISER BASKET 50 SEGMENT (SET OF 6 BASKETS)	
A78410026	5 LITRE REAGENT BOTTLE - EMPTY (SET OF 6 BOTTLES)	
A84110045	DOWNDRAFT EXTRACTION DUCT ADAPTOR KIT	
A78410095	LEVEL SENSOR CLEANING PAD	
A84110032	MEGA BASKET (SET OF 6 BASKETS)	
P09046	SPATULA	