EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746

epredia
Enhancing precision cancer diagnostics

Legal Manufacturer's Name: Richard-Allan Scientific LLC, a subsidiary of Epredia
Legal Manufacturer's Address: 4481 Campus Drive, Kalamazoo, Michigan 49008 USA
SRN (Single Registration Number): US-MF-000008261

Richard-Allan Scientific LLC, 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	Histology Stains (Eosin)
Intended Purpose	Eosin is intended to be used as a cytoplasmic stain for the diagnosis of general pathology specimens.
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	As per Appendix 1– Device Information
Basic UDI-DI	0673693RAS027RR
Nomenclature	GMDN 43587, Biological stain IVD
Initial CE Release Date	2004
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 that provides for the issuing of this EU Declaration of Conformity:

- REACH 1907/2006
- CLP 1272/2008

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 and Regulatory

Place of Issue: Kalamazoo, USA

Date of Issue: 17-May-2022

Revision: 1.0

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- **Appendix 1 – Device Information:**

Catalog Number	Product Name	UDI-DI (GTIN) Code	GMDN Code
71225	Eosin-Y Alcoholic (Series R)	00673693087384	43587
71211	Eosin-Y Alcoholic (Series R)	00673693087377	
71204	Eosin-Y Alcoholic (Series R)	00673693087360	
6766008	Eosin Y Alcoholic (Series S)	00673693228596	
6766007	Eosin Y Alcoholic (Series S)	00673693228589	
71304	Eosin-Y with Phloxine (Series R)	00673693087391	
71311	Eosin-Y with Phloxine (Series R)	00673693087407	
7111	Eosin-Y	00673693087346	
7111L	Eosin-Y	00673693483209	
71504	Eosin-Y Saturated (Series R)	00673693087445	
6766010	Eosin Y Aqueous (Series S)	00673693228619	
6766009	Eosin Y Aqueous (Series S)	00673693228602	
6765040	Instant Eosin Alcoholic (Series S)	00673693228503	
6765540	Instant Eosin Aqueous (Series S)	00673693228510	