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 Trade Name	Differentiating Solutions
Intended Purpose	Differentiating Solution is intended to be used as an aid in hematoxylin staining for the diagnosis of general pathology specimens.
Classification & Classification Rules	Non-Annex II/Non-Self-Test Device
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	0673693RAS026RP
Nomenclature	GMDN 43587, Biological stain IVD GMDN 43606, Differentiation Solutions IVD GMDN 43584, Acid -Alcohol solution 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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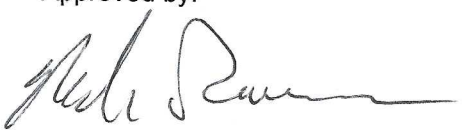
We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746. The devices specified in the product list also conform to the Regulation (EC) No 1907/2006 REACH that provides for the issuing of this EU Declaration of Conformity.

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: 6-February-2023

Revision: 2.0

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- **Appendix 1 – Device Information:**

Catalog Number	Product Name	UDI-DI (GTIN) Code	GMDN Code
7301	Bluing Reagent	00673693088084	43587
7341	Bluing Reagent	00673693088091	43587
7301L	Bluing Reagent	00673693483247	43587
6769002	Bluing Reagent	00673693228688	43587
6769001	Bluing Reagent	00673693228671	43587
7401	Clarifier™ 1	00673693088114	43606
7441	Clarifier™ 1	00673693088152	43606
7402	Clarifier™ 2	00673693088121	43584
7402L	Clarifier™ 2	00673693483315	43584
7442	Clarifier™ 2	00673693088176	43584
6769008	Nu-Clear™ I	00673693228718	43584
6769009	Nu-Clear™ II	00673693228725	43584
74204	Differentiating Solution	00673693088138	43584
74211	Differentiating Solution	00673693088145	43584
88117	Differentiating Solution	00673693169080	43584