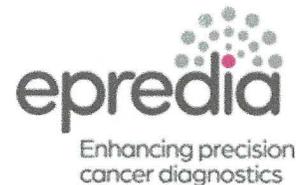


EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746



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	Periodic Acid- Schiff Stain Kit
Intended Purpose	Intended for use as an aid in the identification of carbohydrates, glycogen, basement membranes and fungus in tissue sections 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	0673693RAS049S3
Nomenclature	GMDN 43587, Biological Stain IVD
Initial CE Release Date	2010
Authorized Representative Name and Address	EpreDia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

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



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: 7-June-2022

Revision: 2.0

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:**

Catalog Number	Product Name	UDI-DI (GTIN) Code	GMDN Code
87007	Periodic Acid-Schiff Stain Kit	00673693089173	43587
88016	Periodic Acid Solution	00673693089562	
88017	Schiff Reagent	00673693089586	
88018	Hematoxylin 1	00673693089609	

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