

Part 3 - Declaration of Conformity

Declaration of Conformity

This Declaration of Conformity, issued under the sole responsibility of the manufacturer, is only valid when the IVD is used in accordance with the instructions for use

Manufacturer: Richard-Allan Scientific LLC, a subsidiary of Epredia, 4481 Campus Drive, Kalamazoo, Michigan 49008 USA

Brand Name: Epredia

Authorized Representative: Epredia Netherlands B.V., Essendonk 30, 4824 DA Breda, Netherlands

Notified Body: N/A, Self-Declared

Risk Class: These products are self-declared for compliance to Annex III of the IVDD. These products do not claim any analytes listed in Annex II List A or B and are not intended for self-testing.

Catalog Number	Product Name	UDI-DI (GTIN) Code	EDMA Classification	GMDN Code
RM-2120-R7	PMS2 [EPR3947] RTU 7ml	0673693592161	13.05.01.90	57767
RM-2123-RQ	Anti-Factor XIII A [EP3372] RTU 12ml	0673693706414		
RM-2123-S	Anti-Factor XIII A [EP3372] 1mL	0673693706353		
RM-2123-S0	Anti-Factor XIII A [EP3372] 0.1mL	0673693706377		
RM-2126-R7	p120 Catenin [EP66] RTU 7ml	0673693707336		
TA-125-ADQ	Antibody Diluent OP Quanto	0673693560726		
Intended purpose:	The Richard-Allan Antibodies are intended for qualitative immunohistochemistry with normal and neoplastic formalin-fixed, paraffin-embedded tissue sections, to be viewed by light microscopy.			
Product Common Name:	Richard-Allan Antibodies			
Year of CE Marking:	2016			

In Vitro Diagnostic Directive:	98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full)
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Antibody Products 2016 Forward and Quanto Diluent

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Certificate of REACH Compliance:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
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Issued by: Qin Sun, International Regulatory Director



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