

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		
AP-9003-125	Citrate BuB2:B1045ffer for HIER 125mL	0673693418034	13.05.01.90	57767		
AP-9003-500	Citrate Buffer for HIER 500mL	0673693101783				
AP-9004-125	EDTA Buffer for HIER (10X) 125mL	0673693418041				
AP-9004-500	EDTA Buffer for HIER (10X) 500mL	0673693101790				
AP-9005-050	Tris-HCl Buffer for HIER (10X) 50mL	0673693351881				
AP-9005-125	Tris-HCl Buffer for HIER (10X) 125mL	0673693351898				
AP-9005-500	Tris-HCl Buffer for HIER (10X) 500mL	0673693351904				
AP-9006-002	Protease XXV for Enzyme-Induced Epitope Retrieval 2mL	0673693351911				
AP-9006-005	Protease XXV for Enzyme-Induced Epitope Retrieval 5mL	0673693351928				
AP-9007-005	Pepsin Solution for Enzyme-Induced Epitope Retrieval 5mL	0673693351935				
AP-9009-10	Phosphate Buffered Saline (10X) 10mL	0673693418072				
TA-125-PB	Large Vol Phosphate Buffered Saline (25X) 125mL	0673693418362				
TA-125-PT	Large Vol Phosphate Buffered Saline and Tween 20 (20X) 125mL	0673693418416				
TA-125-TB	Large Vol Tris Buffered Saline (25X) 125mL	0673693418430				
TA-125-TT	Large Vol Tris Buffer Saline and Tween 20 (20X) 125mL	0673693418454				
TA-999-PBQ	UltraVision Protein Block 1L	0673693568364				
TA-999-PT	Phosphate Buffered Saline and Tween 20 Large Vol (20X) 1L	0673693418577				
TA-999-TT	Tris Buffer Saline and Tween 20 Large Vol (20X)1L	0673693111393				
Intended purpose:	For In Vitro Diagnostic Use					
Product Common Name:	Buffers					
Year of CE Marking:	2008					

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

Issued by:

Qin Sun, International Regulatory Affairs Director



Date:

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