

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
See Attachment 1	See Attachment 1	See Attachment 2	13.05.01.90	57767
Intended purpose:	UltraVision Quanto Detection System detects mouse or rabbit antibody bound to an antigen in tissue sections.			
Product Common Name:	UltraVision Quanto Detection System			
Year of CE Marking:	2012			

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 Director

Date:


31 - August - 2020

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Ultravision Quanto Detection Systems

Part 3 - Declaration of Conformity

Attachment 1

Quantity	System/Components	Part Numbers by component size			
		TL-060-QHD	TL-125-QHD	TL-015-QHD	TL-999-QHD
1	UltraVision Quanto Detection System HRP DAB	TA-060-H2O2Q	TA-125-H2O2Q	TA-015-H2O2Q	TA-999-H2O2Q
1	UltraVision Hydrogen Peroxide Block	TA-060-PBQ	TA-125-PBQ	TA-015-PBQ	TA-999-PBQ
1	UltraVision Protein Block	TL-060-QPB	TL-125-QPB	TL-015-QPB	TL-999-QPB
1	Primary Antibody Amplifier Quanto	TL-060-QPH	TL-125-QPH	TL-015-QPH	TL-999-QPH
1	HRP Polymer Quanto	TA-060-QHSX	TA-125-QHSX	TA-015-QHSX	TA-999-QHSX
1	DAB Quanto Substrate	TA-002-QHCX	TA-004-QHCX	TA-001-QHCX	TA-032-QHCX
		TL-060-QHL	TL-125-QHL	TL-999-QHL	
1	UltraVision Quanto Detection System HRP				
1	UltraVision Protein Block	TA-060-PBQ	TA-125-PBQ	TA-999-PBQ	
1	Primary Antibody Amplifier Quanto	TL-060-QPB	TL-125-QPB	TL-999-QPB	
1	HRP Polymer Quanto	TL-060-QPH	TL-125-QPH	TL-999-QPH	
		TL-060-QAL	TL-125-QAL	TL-999-QAL	
1	UltraVision Quanto Detection System AP				
1	Ultra V Block	TA-060-PBQ	TA-125-PBQ	TA-999-PBQ	
1	Primary Antibody Amplifier Quanto	TL-060-QPB	TL-125-QPB	TL-999-QPB	
1	AP Polymer Quanto	TL-060-QAP	TL-125-QAP	TL-999-QAP	
	UltraVision Hydrogen Peroxide Block	TA-060-H2O2Q	TA-125-H2O2Q		
	UltraVision Protein Block	TA-060-PBQ	TA-125-PBQ	TA-999-PBQ	

Attachment 2

Ultravision Quanto Detection Systems

Part 3 - Declaration of Conformity

Catalog Number	Product Name	UDI-DI (GTIN) Code
TA-060-H2O2Q	UV Hydrogen Peroxide Block 60ml	0673693568401
TA-060-PBQ	UltraVision Protein Block 60ml	0673693568333
TA-125-H2O2Q	UV Hydrogen Peroxide Block 125ml	0673693568418
TA-125-PBQ	UltraVision Protein Block 125ml	0673693568357
TL-015-QHD	UltraVision Quanto Detection System HRP DAB Sample 15mL	0673693461108
TL-060-QAL	UltraVision Quanto Detection System AP 60mL	0673693461139
TL-060-QHD	UltraVision Quanto Detection System HRP DAB 60mL	0673693461115
TL-060-QHL	UltraVision Quanto Detection System HRP 60mL	0673693461085
TL-125-QAL	UltraVision Quanto Detection System AP 125mL	0673693461146
TL-125-QHD	UltraVision Quanto Detection System HRP DAB 125mL	0673693461122
TL-125-QHL	UltraVision Quanto Detection System HRP 125mL	0673693461092
TL-999-QAL	UltraVision Quanto Detection System AP 1L	0673693557849
TL-999-QHD	UltraVision Quanto HRP DAB 1L	0673693560542
TL-999-QHL	UltraVision Quanto Detection System HRP 1L	0673693554824