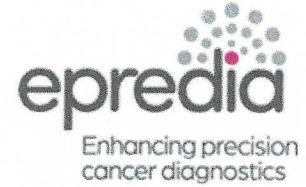


# EU Declaration of Conformity

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

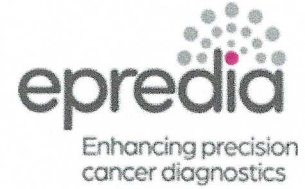
Richard-Allan Scientific LLC, a subsidiary of EpreDia declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

Product and Trade Name	Blades and Knives
Intended Purpose	For in vitro diagnostic use. For use with microtomes and cryostats in the preparation of 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	0673693RAS017RN
Nomenclature	GMDN 42440, Microtome blade IVD, single-use GMDN 42439, Microtome blade IVD, reusable
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:

Place of Issue: Kalamazoo, USA

Mark Ramser

Date of Issue: 17-May-2022

Vice President Quality and Regulatory

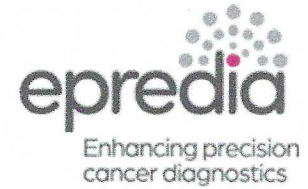
Revision: 1.0

A handwritten signature in black ink, appearing to read "Mark Ramser", is written over the printed name and title.

<b>Form Name</b>	EU Declaration of Conformity	<b>Form (Template) Number</b>	GL-FRM-27-0003	<b>Form Template Version</b>	2.0
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# EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



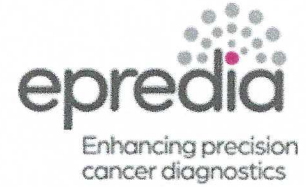
- Appendix 1 – Device Information:**

Catalog Number	Product Name	UDI-DI (GTIN) Code	GMDN Code
4280L	Edge-Rite™ Low Profile Disposable Microtome Blades	00673693074384	42440
4275H	Edge-Rite™ High Profile Disposable Microtome Blades	00673693074322	
1001259	Premium High Profile Microtome Blades	00673693214995	
1001593	Premium High Profile Microtome Blades with PTFE coating	00673693215466	
3150734	HP35 Coated Microtome Blade	00673693222549	
3151735	HP35N Ultra Microtome Blade	00673693591508	
3051835	MX35 Premier Microtome Blade	00673693221696	
3050835	MB DynaSharp Microtome Blade	00673693221672	
3050822	MB22 Premier Microtome Blade	00673693221665	
3052835	MX35 Premier+ Microtome Blade	00673693221702	
3053835	MX35 Ultra Microtome Blade	00673693458856	
3153735	HP35 Ultra Microtome Blade	00673693221696	
7702	Standard Microtome Knife 125 mm	00673693233149	42439
7704	Standard Microtome Knife 250 mm	00673693233187	
7619	Stainless-Steel Microtome Knives 12.5 cm	00673693232913	
7719	Stainless-Steel Microtome Knives 18.5 cm	00673693233200	
2222004	Microtome Knife D-Profile 160 mm	00673693220507	
2222005	Microtome Knife C-Profile 240 mm	00673693220514	
2222006	Microtome Knife D-Profile 240mm	00673693263177	

<b>Form Name</b>	EU Declaration of Conformity	<b>Form (Template) Number</b>	GL-FRM-27-0003	<b>Form Template Version</b>	2.0
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# EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



Catalog Number	Product Name	UDI-DI (GTIN) Code	GMDN Code
5601006	Tungsten Carbide D-Profile Microtome Knives	00673693226707	42439
152010	Microtome Knife, 12 CM, C	00673693063494	
152020	Microtome Knife, 16 CM, C	00673693063500	
152050	Microtome Knife, 30CM, C	00673693063753	
152060	Microtome Knife, 12 CM, D	00673693063760	
152070	Microtome Knife, 16 CM, D	00673693063777	
152080	Microtome Knife, 22 CM, D	00673693063784	
152090	Microtome Knife, 25 CM, D	00673693063791	
152100	Microtome Knife, 30 CM, D	00673693063807	
152120	Tungsten Carbide Knife, 16 CM	00673693063814	
160010	Adamas Blades for Disposable Magnetic Blade Carriers 60 mm 10/cs	00673693064200	
160020	Adamas Blades for Disposable Magnetic Blade Carriers 60 mm 50/cs	00673693064217	
160040	Adamas Blades for Disposable Magnetic Blade Carriers 80 mm 10/cs	00673693064231	
160050	Adamas Blades for Disposable Magnetic Blade Carriers 80 mm 50/cs	00673693329538	

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