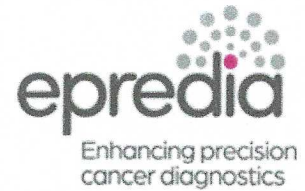


EU Declaration of Conformity

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

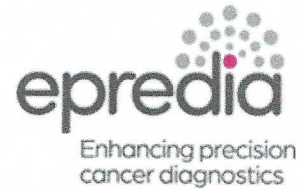
Richard-Allan Scientific LLC, a subsidiary of Epredia declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled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

Product and Trade Name	Embedding consumables
Intended Purpose	For use 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	0673693RAS019RS
Nomenclature	GMDN 63791, Tissue embedding mould IVD, single-use GMDN 63792, Tissue embedding mould IVD, reusable GMDN 63813, Tissue embedding mould holder IVD
Initial CE Release Date	2004
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

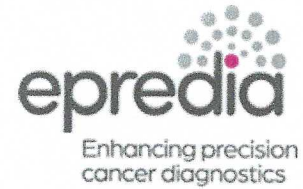
Revision: 1.0

A handwritten signature in black ink, appearing to read "Mark Ramser", written over a horizontal line.

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
58950	Disposable Base Molds	00673693083751	63791
58951	Disposable Base Molds	00673693083768	63791
58952	Disposable Base Molds	00673693083775	63791
58953	Disposable Base Molds	00673693083782	63791
6401015	Stainless Steel Base Molds	00673693227506	63792
6401016	Stainless Steel Base Molds	00673693227513	63792
6401017	Stainless Steel Base Molds	00673693227520	63792
6401018	Stainless Steel Base Molds	00673693227537	63792
41740	Disposable Base Molds	00673693224116	63791
41741	Disposable Base Molds	00673693224123	63791
41742	Disposable Base Molds	00673693224130	63791
41743	Disposable Base Molds	00673693224147	63791
41744	Disposable Base Molds	00673693224154	63791
1220	Peel-A-Way™ Disposable Embedding Molds	00673693218368	63791
2219	Peel-A-Way™ Disposable Embedding Molds	00673693220460	63791
1830	Peel-A-Way™ Disposable Embedding Molds	00673693219310	63791
1841	Peel-A-Way™ Disposable Embedding Molds	00673693219327	63791
1000956	Embedding Rings Blue	00673693214254	63813

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