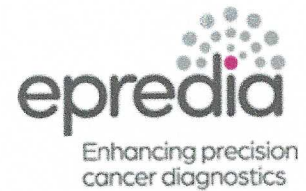


EU Declaration of Conformity

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

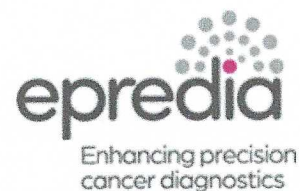
Richard-Allan Scientific LLC, a subsidiary of EpreDia declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled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

Product and Trade Name	Cassettes
Intended Purpose	For the preparation of pathology specimens.
Classification & Classification Rules	Class A, Rule 5, Indent (c)
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	0673693RAS001R7
Nomenclature	GMDN 62970, Histology tissue cassette IVD GMDN 63813, Tissue embedding mould holder IVD GMDN 63784, Histological tissue cassette biopsy insert IVD
Initial CE Release Date	2018
Authorized Representative Name and Address	EpreDia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

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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.

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:

Mark Ramser
Vice President Quality and Regulatory

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

Place of Issue: Kalamazoo, USA

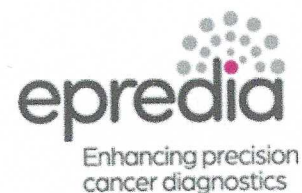
Date of Issue: 17-May-2022

Revision: 1.0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
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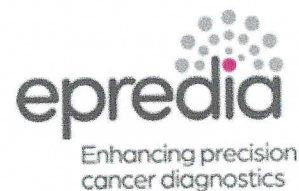
• **Appendix 1 – Device Information:**

Catalog Number	Product Name	UDI-DI-(GTIN) Code	GMDN Code
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B851040BL	PrintMate™ Embedding Cassette	00673693757805	
B851040GN	PrintMate™ Embedding Cassette	00673693757812	
B851040GY	PrintMate™ Embedding Cassette	00673693757829	
B851040LA	PrintMate™ Embedding Cassette	00673693757799	
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B851040OR	PrintMate™ Embedding Cassette	00673693757843	
B851040PK	PrintMate™ Embedding Cassette	00673693757850	
B851040TN	PrintMate™ Embedding Cassette	00673693757867	
B851040WH	PrintMate™ Embedding Cassette	00673693757782	
B851040YW	PrintMate™ Embedding Cassette	00673693757874	
B851010BE	PrintMate™ Embedding Cassette	00673693758185	
B851010BL	PrintMate™ Embedding Cassette	00673693757164	
B851010GN	PrintMate™ Embedding Cassette	00673693757171	
B851010GY	PrintMate™ Embedding Cassette	00673693757188	
B851010LA	PrintMate™ Embedding Cassette	00673693757157	
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B851010WH	PrintMate™ Embedding Cassette	00673693754880	
B851010YW	PrintMate™ Embedding Cassette	00673693757232	
B851070BE	PrintMate™ Embedding Cassette	00673693758123	62970
B851070BL	PrintMate™ Embedding Cassette	00673693757515	
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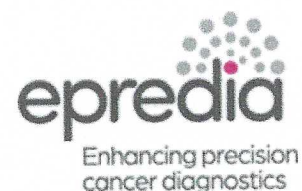


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B851070TN	PrintMate™ Embedding Cassette	00673693757577
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B851100LA	PrintMate™ Embedding Cassette	00673693757249
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B851100LI	PrintMate™ Embedding Cassette	00673693757287
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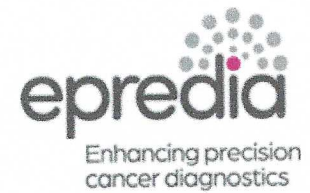


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B851120WH	PrintMate™ Slotted Cassette	00673693754897	
B851120YW	PrintMate™ Slotted Cassette	00673693757492	
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B851080BL	PrintMate™ Biopsy Cassette	00673693757607	
B851080GN	PrintMate™ Biopsy Cassette	00673693757614	
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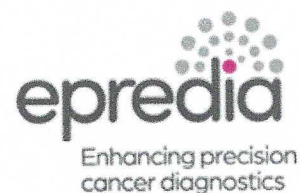


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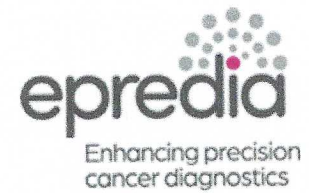


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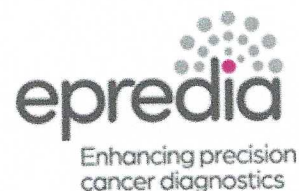


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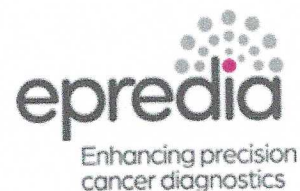


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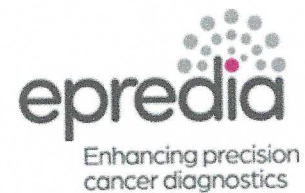


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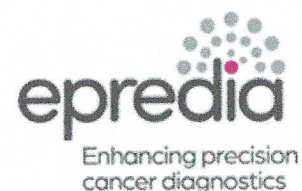


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B851750LA	TissueLoc™ Biopsy Cassette	00673693757133	
B851750LG	TissueLoc™ Biopsy Cassette	00673693757966	
B851750LI	TissueLoc™ Biopsy Cassette	00673693757126	
B851750OR	TissueLoc™ Biopsy Cassette	00673693757959	
B851750PK	TissueLoc™ Biopsy Cassette	00673693757096	
B851750TN	TissueLoc™ Biopsy Cassette	00673693757102	
B851750WH	TissueLoc™ Biopsy Cassette	00673693757058	
B851750YW	TissueLoc™ Biopsy Cassette	00673693757072	
1000957	Tissue Cassette I	00673693214261	
1000958	Tissue Cassette I	00673693214278	
1000959	Tissue Cassette I	00673693214285	
1000960	Tissue Cassette I	00673693214292	
1000961	Tissue Cassette I	00673693214308	
1000962	Tissue Cassette I	00673693214315	
1000963	Tissue Cassette I	00673693214322	
1000964	Tissue Cassette I	00673693214339	
1000965	Tissue Cassette I	00673693214346	62970
1000966	Tissue Cassette I	00673693214353	
1000967	Tissue Cassette I	00673693214360	
1000968	Biopsy Cassette I	00673693214377	
1000969	Biopsy Cassette I	00673693214384	
1000970	Biopsy Cassette I	00673693214391	
1000971	Biopsy Cassette I	00673693214407	
1001090	Biopsy Cassette I	00673693214612	
1001091	Biopsy Cassette I	00673693214629	
1001092	Biopsy Cassette I	00673693214636	
1001094	Biopsy Cassette I	00673693214650	
1001095	Biopsy Cassette I	00673693214667	

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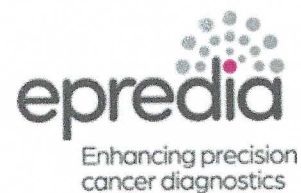


1001096	Biopsy Cassette I	00673693214674	
1001051C	Cassette II Tissue	00673693687799	
1001052C	Cassette II Tissue	00673693687782	
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1001054C	Cassette II Tissue	00673693687768	
1001055C	Cassette II Tissue	00673693687751	
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1001061C	Cassette II Tissue	00673693687683	
1001051CLS	Cassette II Tissue	00673693687652	
1001052CLS	Cassette II Tissue	00673693687645	
1001053CLS	Cassette II Tissue	00673693687638	
1001054CLS	Cassette II Tissue	00673693687621	
1001055CLS	Cassette II Tissue	00673693687614	
1001056CLS	Cassette II Tissue	00673693687607	
1001057CLS	Cassette II Tissue	00673693687591	
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1001059CLS	Cassette II Tissue	00673693687584	
1001060CLS	Cassette II Tissue	00673693687577	
1001061CLS	Cassette II Tissue	00673693687553	
B1003500AQ	Embedding Cassettes without Lids	00673693245289	
B1003500BL	Embedding Cassettes without Lids	00673693245296	
B1003500GR	Embedding Cassettes without Lids	00673693245326	
B1003500LI	Embedding Cassettes without Lids	00673693245340	
B1003500PE	Embedding Cassettes without Lids	00673693245364	
B1003500PK	Embedding Cassettes without Lids	00673693245371	

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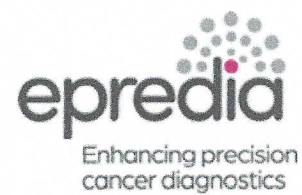


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B1000732BL	Embedding Cassettes without Lids	00673693243810	
B1000732GR	Embedding Cassettes without Lids	00673693243827	
B1000732GY	Embedding Cassettes without Lids	00673693243834	
B1000732LI	Embedding Cassettes without Lids	00673693243841	
B1000732OR	Embedding Cassettes without Lids	00673693243858	
B1000732PE	Embedding Cassettes without Lids	00673693243865	
B1000732PK	Embedding Cassettes without Lids	00673693243872	
B1000732TN	Embedding Cassettes without Lids	00673693243889	
B1000732WH	Embedding Cassettes without Lids	00673693243896	
B1000732YW	Embedding Cassettes without Lids	00673693243902	
B1000732WHCPL	Embedding Cassettes without Lids	00673693744522	
B1000732LICPL	Embedding Cassettes without Lids	00673693744539	
B1000732ORCPL	Embedding Cassettes without Lids	00673693744546	
B1000732PKCPL	Embedding Cassettes without Lids	00673693744553	
B1000732TNCPL	Embedding Cassettes without Lids	00673693744560	
B1000732GYCPL	Embedding Cassettes without Lids	00673693744577	
B1000732YWCPL	Embedding Cassettes without Lids	00673693750868	
1001003	Metal Lids	00673693214469	62970

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1000956	Embedding Rings	00673693214254	63813
8453	Tissue Capsule pads	00673693235068	63784

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