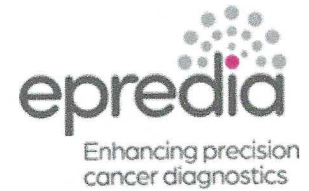


EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



Legal Manufacturer's Name: New Eire Scientific LLC
Legal Manufacturer's Address: 20 Post Road, Portsmouth, NH 03801 USA
SRN (Single Registration Number): US-MF-000008165

New Eire Scientific LLC 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.

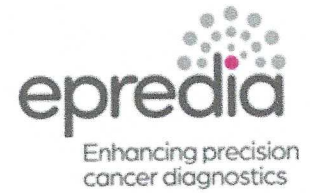
Product and Trade Name	Adhesion Microscope Slides (Trade Name: see Appendix 1 – Device Information)
Intended Purpose	Microscope Adhesion slides electrostatically attract fresh, frozen and formalin fixed paraffin embedded tissue sections, binding them to the slide. They are intended for in vitro diagnostic use by clinical and diagnostic laboratories who require high quality slides to hold and view clinical 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	081004133NES001MN
Nomenclature	GMDN 57925 - Microscope Slides
Initial CE Release Date	2000
Authorized Representative Name and Address	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands
Authorized Representative SRN	NL-AR-000001488

We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746.

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

Mark Ramser
Vice President, Quality & Regulatory

Date of Issue: 13-May-2022

Revision: 01

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

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:**

Product Name	Product Number
Superfrost Plus blue	J1810AMNZTR
Superfrost Plus violet	J1860ARLX
Superfrost Plus green CC	J7840AMNZ
Superfrost Plus white	J1800AMNZ
Superfrost Plus white	J1800ABDH
Superfrost Plus white	J1800ARLX
Polysine white	J2800AMNZ
Superfrost Plus yellow	J1830AMNZ
Superfrost Plus blue	J1810AMNZ
Superfrost Plus white	J1800AAUT
Superfrost Plus pink	J1820AMNZ
Superfrost Plus white	J1800AHTX
Superfrost Plus green	J1840AMNZ
Superfrost Plus white CC	J7800AMNZ
Polysine white	J2800ABDH
Superfrost Plus white	J1800AMNZTR
Superfrost Plus blue	J1810ABDH
Superfrost Excell white	J5800AMNZ
Superfrost Plus pink	J1820ABDH
Superfrost Plus yellow	J1830ABDH
Superfrost Plus green	J1840ABDH
Superfrost Plus orange CC	J7850AMNZ
Polysine white	J2800ARLX
Superfrost Plus blue	J1810ARLX
Superfrost Plus orange	J1850AMNZ
Superfrost Plus 51 x 75 mm	J1800BMNZ
Superfrost Plus yellow	J1830ARLX
Superfrost Plus green CC	J7840ARLX
Polysine white	J2800AHTX
Superfrost Plus green	J1840ARLX

Product Name	Product Number
Diagnostic Speciality Slides	X5ES2030LAD1
Diagnostic Speciality Slides	X5ES2115BAD1
Diagnostic Speciality Slides	X5ES2165BAD1
Diagnostic Speciality Slides	X5ES242BAD1
Diagnostic Speciality Slides	X5ES248BAD1
Diagnostic Speciality Slides	X5XER201BAD1
Diagnostic Speciality Slides	X5XER202LCC2
Diagnostic Speciality Slides	X5XER202WAD1
Diagnostic Speciality Slides	X5XER203BAD1
Diagnostic Speciality Slides	X5XMZ231LCC2
Colorfrost Plus Slides	9991015
Colorfrost Plus Slides	9991014
Colorfrost Plus Slides	9991012
Colorfrost Plus Slides	9991011
Colorfrost Plus Slides	9991013
Colorfrost Plus Slides	9991009
Colorfrost Plus Slides	9991002
Colorfrost Plus Slides	9991004
Colorfrost Plus Slides	9991001
Colorfrost Plus Slides	9991003
Colormark Plus Slides	B9992010TN
Colormark Plus Slides	B9992010RD
Colormark Plus Slides	B9992010LV
Colormark Plus Slides	B9992010BO
Colormark Plus Slides	B9992010AQ
Colormark Plus Slides	B9992010PK
Colormark Plus Slides	B9992010GR
Colormark Plus Slides	B9992010GL
Colormark Plus Slides	B9992010BL
Colormark Plus Slides	B9992010

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Product Name	Product Number
Superfrost Plus pink	J1820ARLX
Superfrost Plus 38 x 75 mm	J1800CMNZ
Superfrost Plus orange	J1850ARLX
Superfrost Plus violet	J1860AMNZ
Capillary-gap Slidesgrau 75 µm	J6409741WGYPLUS
Capillary-gap Slidesblue 100 µm	J6815741WPLUS
Superfrost Plus GOLD white	K5800AMNZ72
SlideMate Slides	TT-40418218-PS-W

Product Name	Product Number
Colormark Plus Slides	B9992010YW
Colormark Slides	B9992010PKSUNC
Cytoslide	5991056
DoubleCytoslide	5991055
Polysine Slides	6776216
Polysine Slides	6776215
Superfrost Plus Slides	6776214
Superfrost Plus Slides	9991000

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