

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.

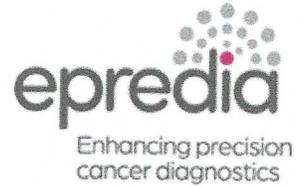
Product and Trade Name	Non-Adhesion Microscope Slides (Trade Name: see Appendix 1 – Device Information)
Intended Purpose	Non Adhesion microscope slides are intended for in vitro diagnostic use by clinical and diagnostic laboratories who require high quality slides to hold and view clinical specimens.
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

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1. Appendix 1 – Device Information:

Product Name	Product Number
Microscope Slides	AA00000102E01MNZ11
Microscope Slides	AA00000112E01MNZ10
Microscope Slides	AA00000102E01MNZ10
Microscope Slides	AG00000112E04CML20
Microscope Slides	AA00000102E01MNZ21
Microscope Slides	AG00000112E01MNZ10
Microscope Slides	AB00000112E01MNZ10
Microscope Slides	AA00000112E01MNZ51
Microscope Slides	AB00000106E01MNZ51
Microscope Slides	AA00000112E01CML20
Microscope Slides	AA00000112E04MNZ50
Microscope Slides	AA00000112E01MNZ21
Microscope Slides	AA00000112E01MNZ11
Microscope Slides	AB00000112E01CLI10
Microscope Slides	AB00000112E04CML20
Microscope Slides	AA00000112E01CML10
Microscope Slides	AF00000112E04CML20
Microscope Slides	AA00000102E01CML20
Microscope Slides	AA00000102E01FST20
Microscope Slides	AA00000102E01CML10

Product Name	Product Number
Superfrost™ Microscope Slides	AF00008332E01MNZ20
Superfrost™ Microscope Slides	AA00008432E01MNZ21
Superfrost™ Microscope Slides	AB00008132E01MNZ21
Superfrost™ Microscope Slides	AG00008632E04CML20
Superfrost™ Microscope Slides	AA00008032E04CLI20
Superfrost™ Microscope Slides	AG00008532E01MNZ21
Superfrost™ Microscope Slides	AA00008032E01MNR10
Superfrost™ Microscope Slides	AA00008532E01MNZ11
Superfrost™ Microscope Slides	AG00008532E01MNZ20
Superfrost™ Microscope Slides	AB00008332E04MNZ10
Superfrost™ Microscope Slides	AB00008532E01MNZ10
Superfrost™ Microscope Slides	AB00008532E04CML20
Superfrost™ Microscope Slides	AB00008532E01MNZ20
Superfrost™ Microscope Slides	AF00008332E01MNZ10
Superfrost™ Microscope Slides	AG00008332E01MNZ11
Superfrost™ Microscope Slides	AF00008432E01MNZ20
Superfrost™ Microscope Slides	AG00008132E01MNZ11
Superfrost™ Microscope Slides	AG00008232E01FST20
Superfrost™ Microscope Slides	AA00008132E04MNZ10
Superfrost™ Microscope Slides	AA00008332E01MNZ50

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Product Name	Product Number
Microscope Slides	AB00000112E01MNR10
Microscope Slides	AB00000112E01MNZ11
Microscope Slides	AG00000102E01MNZ10
Microscope Slides	AB00000102E01MNZ10
Microscope Slides	AG00000102E04CML20
Microscope Slides	AF00000112E04MNZ10
Microscope Slides	AG00000112E01MNZ11
Microscope Slides	AA00000112E01CLI10
Microscope Slides	AA00000112E01MNZ20
Microscope Slides	AA00000112E01CML21
Microscope Slides	AB00000112E01MNZ20
Microscope Slides	AB00000112E01MNZ21
Microscope Slides	AG00000112E04CML21
Microscope Slides	AA00000112E01MNR10
Microscope Slides	AG00000112E01MNR10
Microscope Slides	AB00000112E01CLI20
Microscope Slides	AA00000102E04MNZ10
Microscope Slides	AB00000102E01CLI10
Microscope Slides	AB00000102E04CML20
Microscope Slides	AB00000102E01MNZ20
Microscope Slides	AB00000112E04MNZ10

Product Name	Product Number
Superfrost™ Microscope Slides	AG00008032E01MNR10
Superfrost™ Microscope Slides	AA00008232E01MNZ21
Superfrost™ Microscope Slides	AF00008032E04MNZ20
Superfrost™ Microscope Slides	AA00008532E04MNZ10
Superfrost™ Microscope Slides	AB00008632E01MNZ20
Superfrost™ Microscope Slides	AB00008432E04CML21
Superfrost™ Microscope Slides	AA00008332E01MNZ20
Superfrost™ Microscope Slides	AB00008332E01NZT21
Superfrost™ Microscope Slides	AG00008432E01FST20
Superfrost™ Microscope Slides	AF00008032E01MNZ20
Superfrost™ Microscope Slides	AG00008332E01CLI10
Superfrost™ Microscope Slides	AG00008032E04CML21
Superfrost™ Microscope Slides	AB00008232E04MNZ10
Superfrost™ Microscope Slides	AA00008532E01MNZ20
Superfrost™ Microscope Slides	AF00008232E01MNZ10
Superfrost™ Microscope Slides	AG00008232E01MNZ11
Superfrost™ Microscope Slides	AA00008232E01MNZ20
Superfrost™ Microscope Slides	AA00008232E01NZT21
Superfrost™ Microscope Slides	AB00008132E04MNZ10
Superfrost™ Microscope Slides	AG00008132E04MNZ51
Superfrost™ Microscope Slides	AG00008332E04MNZ51

Form Name	EU Declaration of Conformity	Form Number	GL-FRM-27-0003	Form Revision	2
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Product Name	Product Number
Microscope Slides	AG00000112E04MNZ10
Microscope Slides	AA00000102E01CLI10
Microscope Slides	AG00000102E01MNZ21
Microscope Slides	AA00000112E04MNZ10
Microscope Slides	AB00000102E01MNZ21
Microscope Slides	AG00000112E01MNZ20
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Microscope Slides	AA00000102E01MNZ20
Microscope Slides	AB00000112E04CML21
Microscope Slides	AF00000102E01MNZ10
Microscope Slides	AG00000112E01MNZ21

Product Name	Product Number
Superfrost™ Microscope Slides	AG00008432E04MNZ51
Superfrost™ Microscope Slides	AB00008032E04MNZ20
Superfrost™ Microscope Slides	AF00008432E04MNZ20
Superfrost™ Microscope Slides	AA00008032E01MNZ20
Superfrost™ Microscope Slides	AA00008332E04MNZ10
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Superfrost™ Microscope Slides	AG00008532E04MNZ51
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Superfrost™ Microscope Slides	AF00008432E01MNZ10

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Product Name	Product Number
Microscope Slides	AG00000102E01MNZ50
Microscope Slides	AA00000102E01MNZ50
Microscope Slides	AA00008332E01CLI20
Microscope Slides	AB00000102E04MNZ10
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Microscope Slides	AF00000102E01MNZ20
Microscope Slides	AG00000102E04MNZ51
Microscope Slides	AG00000112E01MNZ51
Microscope Slides	AG00000112E04MNZ51
Superfrost™ Microscope Slides	AF00008032E04CML20
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Product Name	Product Number
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Superfrost™ Microscope Slides	AF00008132E01MNZ50
Superfrost™ Microscope Slides	AG00008632E01MNZ20
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Superfrost™ Microscope Slides	AF00008432E01MNZ50
Superfrost™ Microscope Slides	AG00008632E01MNZ10
Superfrost™ Microscope Slides	AA00008032E01NZZ21
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Superfrost™ Microscope Slides	AA00008032E01MNZ50
Superfrost™ Microscope Slides	AF00008132E04MNZ20
Superfrost™ Microscope Slides	AA00008432E01MNZ50
Superfrost™ Microscope Slides	AG00008032E01MNZ50
Superfrost™ Microscope Slides	AA00008432E01NZZ21
Superfrost™ Microscope Slides	AA00008532E01MNZ50
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Superfrost™ Microscope Slides	AB00008632E01MNZ10
Superfrost™ Microscope Slides	AA00008232E01MNZ50
Superfrost™ Microscope Slides	AB00008132E01MNZ50
Superfrost™ Microscope Slides	AB00008432E01MNZ51

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Product Name	Product Number
Superfrost™ Microscope Slides	AA00008032E04MNZ50
Superfrost™ Microscope Slides	AG00008032E04CML20
Superfrost™ Microscope Slides	AA00008132E01NZT21
Superfrost™ Microscope Slides	AA00008032E04CML20
Superfrost™ Microscope Slides	AA00008032E01MNZ21
Superfrost™ Microscope Slides	AB00008032E01CLI10
Superfrost™ Microscope Slides	AG00008032E01MNZ11
Superfrost™ Microscope Slides	AA00008432E01MNZ10
Superfrost™ Microscope Slides	AA00008232E04CLI20
Superfrost™ Microscope Slides	AA00008232E04MNZ10
Superfrost™ Microscope Slides	AA00008232E04MNZ20
Superfrost™ Microscope Slides	AA00008132E01MNZ10
Superfrost™ Microscope Slides	AA00008332E04CLI20
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Product Name	Product Number
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Superfrost™ Microscope Slides	AB00008332E04MNZ20
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Superfrost™ Microscope Slides	AB00008032E01NZT21
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Superfrost™ Microscope Slides	AG00008232E01MNZ50
Superfrost™ Microscope Slides	AG00008332E04CML21
Superfrost™ Microscope Slides	AB00008632E01MNZ50
Superfrost™ Microscope Slides	AG00008432E01MNZ50
Diagnostic Speciality Slides	X1XCM321L

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Product Name	Product Number
Superfrost™ Microscope Slides	AB00008332E04CML20
Superfrost™ Microscope Slides	AA00008632E04MNZ10
Superfrost™ Microscope Slides	AG00008032E01MNZ20
Superfrost™ Microscope Slides	AG00008132E01MNZ1
Superfrost™ Microscope Slides	AG00008332E04CML20
Superfrost™ Microscope Slides	AA00008132E01MNZ11
Superfrost™ Microscope Slides	AG00008332E01MNZ21
Superfrost™ Microscope Slides	AA00008132E01MNZ21
Superfrost™ Microscope Slides	AA00008332E04CML20
Superfrost™ Microscope Slides	AB00008432E01MNZ10
Superfrost™ Microscope Slides	AB00008032E01MNZ20
Superfrost™ Microscope Slides	AB00008232E04CML20
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Superfrost™ Microscope Slides	AG00008032E04MNZ51
Superfrost™ Microscope Slides	AG00008132E01MNZ10
Superfrost™ Microscope Slides	AB00008132E04MNZ20
Superfrost™ Microscope Slides	AB00008332E01CL110
Superfrost™ Microscope Slides	AA00008132E04CML20

Product Name	Product Number
Diagnostic Speciality Slides	X1XCM3240
Diagnostic Speciality Slides	X1XER301B
Diagnostic Speciality Slides	X1XER301R
Diagnostic Speciality Slides	X1XER302W
Diagnostic Speciality Slides	X1XER303B
Diagnostic Speciality Slides	X1XER304B
Diagnostic Speciality Slides	X1XER305B
Diagnostic Speciality Slides	X1XER305L
Diagnostic Speciality Slides	X1XER306W
Diagnostic Speciality Slides	X1XER307W
Diagnostic Speciality Slides	X1XER308B
Diagnostic Speciality Slides	X1XER309B
Diagnostic Speciality Slides	X1XER311B
Diagnostic Speciality Slides	X1XER312B
Diagnostic Speciality Slides	X1XER313B
Diagnostic Speciality Slides	X1XER314B
Diagnostic Speciality Slides	X1XER314W
Diagnostic Speciality Slides	X1XER315B
Diagnostic Speciality Slides	X1XER315L
Diagnostic Speciality Slides	X1XER332B
Diagnostic Speciality Slides	X1XER332L

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Product Name	Product Number
Superfrost™ Microscope Slides	AB00008432E01MNZ21
Superfrost™ Microscope Slides	AG00008432E04CML20
Superfrost™ Microscope Slides	AA00008532E01MNZ10
Superfrost™ Microscope Slides	AG00008132E04CML20
Superfrost™ Microscope Slides	AB00008432E04MNZ10
Superfrost™ Microscope Slides	AF00008432E04CML20
Superfrost™ Microscope Slides	AB00008532E01CLI10
Superfrost™ Microscope Slides	AB00008532E01MNZ50
Superfrost™ Microscope Slides	AA00008432E04CML20
Superfrost™ Microscope Slides	AG00008232E01MNZ21
Superfrost™ Microscope Slides	AF00008032E01MNZ10
Superfrost™ Microscope Slides	AG00008232E01MNZ20
Superfrost™ Microscope Slides	AB00008232E01MNZ10
Superfrost™ Microscope Slides	AG00008432E01MNZ10
Superfrost™ Microscope Slides	AA00008532E04CML20
Superfrost™ Microscope Slides	AF00008132E01MNZ10
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Superfrost™ Microscope Slides	AF00008332E04CML20
Superfrost™ Microscope Slides	AG00008232E04CML20
Superfrost™ Microscope Slides	AF00008532E01MNZ10

Product Name	Product Number
Diagnostic Speciality Slides	X1XER368B
Diagnostic Speciality Slides	X1XER385W
Diagnostic Speciality Slides	X1XES306W
Diagnostic Speciality Slides	X1XES3105L
Diagnostic Speciality Slides	X1XES3176B
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Diagnostic Speciality Slides	X2XCM210R
Diagnostic Speciality Slides	X2XCM221R
Diagnostic Speciality Slides	X2XER201B
Diagnostic Speciality Slides	X2XER202W
Diagnostic Speciality Slides	X2XER203B
Diagnostic Speciality Slides	X2XER204B
Diagnostic Speciality Slides	X2XER205B
Diagnostic Speciality Slides	X2XER207W
Diagnostic Speciality Slides	X2XER208B
Diagnostic Speciality Slides	X2XER209B
Diagnostic Speciality Slides	X2XER215L
Diagnostic Speciality Slides	X2XER240B

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Product Name	Product Number
Superfrost™ Microscope Slides	AF00008532E04MNZ20
Superfrost™ Microscope Slides	AG00008032E01FST20
Superfrost™ Microscope Slides	AA00008232E04CML20
Superfrost™ Microscope Slides	AA00008032E04MNZ10
Superfrost™ Microscope Slides	AA00008632E01MNZ10
Superfrost™ Microscope Slides	AG00008332E01MNZ20
Superfrost™ Microscope Slides	AB00008432E01CLI10
Superfrost™ Microscope Slides	AA00008532E01MNZ21
Superfrost™ Microscope Slides	AG00008232E01MNZ10
Superfrost™ Microscope Slides	AF00008332E04CLI20
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Superfrost™ Microscope Slides	AG00008532E04CML20
Superfrost™ Microscope Slides	AB00008032E04MNZ10
Superfrost™ Microscope Slides	AB00008132E01NZZ21

Product Name	Product Number
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Diagnostic Speciality Slides	X2XER285W
Diagnostic Speciality Slides	X2XES2124W
Diagnostic Speciality Slides	X7X30114HWHTC
Diagnostic Speciality Slides	X7X30141HBHTC
Diagnostic Speciality Slides	X7X3021HRHTC
Diagnostic Speciality Slides	X7X30220HBHTC
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Diagnostic Speciality Slides	X8X301179ARCE
Diagnostic Speciality Slides	X8X3012ABCE
Diagnostic Speciality Slides	X8X3021AWCE
Diagnostic Speciality Slides	X8X30226ABCE
Diagnostic Speciality Slides	X8X30405ABCE
Diagnostic Speciality Slides	X8X3042HRHTC

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EU Declaration of Conformity	GL-FRM-27-0003	2

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Product Name	Product Number
Superfrost™ Microscope Slides	AB00008432E04CML20
Superfrost™ Microscope Slides	AG00008532E01MNR10
Superfrost™ Microscope Slides	AF00008032E04CLI20
Superfrost™ Microscope Slides	AG00008532E01MNZ50
Superfrost™ Microscope Slides	AG00008532E04MNZ10
Superfrost™ Microscope Slides	AG00008432E01MNZ20
Superfrost™ Microscope Slides	AA00008232E01MNZ11
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Superfrost™ Microscope Slides	AA00008032E01MNZ11
Superfrost™ Microscope Slides	AF00008532E01MNZ50

Product Name	Product Number
Diagnostic Speciality Slides	X8X30503ABCE
Diagnostic Speciality Slides	X8X307ABCE
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Diagnostic Speciality Slides	X8X307HRHTC
Diagnostic Speciality Slides	X8X30819ABCE
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Diagnostic Speciality Slides	30-3456A-BK-CE24
Diagnostic Speciality Slides	30-2818A-BK-CE24
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Diagnostic Speciality Slides	30-2419H-BK-CE24
Diagnostic Speciality Slides	30-1040A-BK-CE24
SlideMate Slides	TT-40418217-W

Form Name	Form Number	Form Revision
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Product Name	Product Number
Superfrost™ Microscope Slides	AF00008532E04CML20
Superfrost™ Microscope Slides	AA00008332E01MNZ11
Superfrost™ Printink Microscope Slides	AF00004032E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004132E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004232E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004332E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004432E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004532E01MNZ51
Superfrost™ Printink Microscope Slides	AF00004632E01MNZ51
Superfrost™ Microscope Slides	AF00008132E01MNZ20
Superfrost™ Microscope Slides	AG00000102E01MNZ51
Superfrost™ Microscope Slides	AG00008032E01MNZ51
Superfrost™ Microscope Slides	AG00008432E01MNZ51

Product Name	Product Number
SupaMega Superfrost Slides	4957-001CE
SupaMega Plain Slides	2957-001CE
Superfrost™ Microscope Slides	AF00008232E01MNZ20
Superfrost™ Microscope Slides	AG00008232E01MNZ51
Superfrost™ Microscope Slides	AG00008332E01MNZ51
Superfrost™ Microscope Slides	AG00008332E01MNZ50
Superfrost™ Microscope Slides	AG00008532E01MNZ51
Superfrost™ Microscope Slides	AB00008432E01MNZ20
Superfrost™ Microscope Slides	AF00008032E01MNZ51
Superfrost™ Microscope Slides	AF00008132E01MNZ51
Superfrost™ Microscope Slides	AF00008232E01MNZ51
Superfrost™ Microscope Slides	AG00008432E01MNR10
Superfrost™ Microscope Slides	AF00008532E01MNZ20

Form Name	Form Number	Form Revision
EU Declaration of Conformity	GL-FRM-27-0003	2