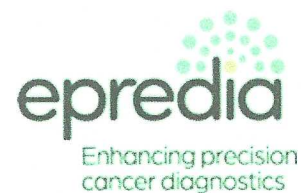


EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



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

New Erie 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.

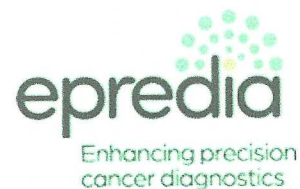
Product and Trade Name	Adhesion Microscope Slides (Trade Name: see Appendix 1 – Device Information)
Intended Purpose	Microscope Adhesion slides electrostatically attract fresh, frozen and formalin fixed paraffin embedded tissue sections, binding them to the slide. They are intended for in vitro diagnostic 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: 5 October 2022

Revision: 4.0

A handwritten signature in blue 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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EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746

• Appendix 1 – Device Information:

No.	Product Name	Product Number
1	Superfrost Plus blue	J1810AMNZTR
2	Superfrost Plus violet	J1860ARLX
3	Superfrost Plus green CC	J7840AMNZ
4	Superfrost Plus white	J1800AMNZ
5	Superfrost Plus white	J1800ABDH
6	Superfrost Plus white	J1800ARLX
7	Polysine white	J2800AMNZ
8	Superfrost Plus yellow	J1830AMNZ
9	Superfrost Plus blue	J1810AMNZ
10	Superfrost Plus white	J1800AAUT
11	Superfrost Plus pink	J1820AMNZ
12	Superfrost Plus white	J1800AHTX
13	Superfrost Plus green	J1840AMNZ
14	Superfrost Plus white CC	J7800AMNZ
15	Polysine white	J2800ABDH
16	Superfrost Plus white	J1800AMNZTR
17	Superfrost Plus blue	J1810ABDH
18	Superfrost Excell white	J5800AMNZ
19	Superfrost Plus pink	J1820ABDH
20	Superfrost Plus yellow	J1830ABDH
21	Superfrost Plus green	J1840ABDH
22	Superfrost Plus orange CC	J7850AMNZ
23	Polysine white	J2800ARLX
24	Superfrost Plus blue	J1810ARLX
25	Superfrost Plus orange	J1850AMNZ
26	Superfrost Plus 51 x 75 mm	J1800BMNZ
27	Superfrost Plus yellow	J1830ARLX
28	Superfrost Plus green CC	J7840ARLX
29	Polysine white	J2800AHTX
30	Superfrost Plus green	J1840ARLX

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To IVD REGULATION (EU) 2017/746

No.	Product Name	Product Number
31	Superfrost Plus pink	J1820ARLX
32	Superfrost Plus 38 x 75 mm	J1800CMNZ
33	Superfrost Plus orange	J1850ARLX
34	Superfrost Plus violet	J1860AMNZ
35	Capillary-gap Slidesgrau 75 µm	J6409741WGYPLUS
36	Capillary-gap Slidesblue 100 µm	J6815741WPLUS
37	Superfrost Plus GOLD white	K5800AMNZ72
38	SlideMate Slides	TT-40418218-PS-W
39	Diagnostic Speciality Slides	X5ES2030LAD1
40	Diagnostic Speciality Slides	X5ES2115BAD1
41	Diagnostic Speciality Slides	X5ES2165BAD1
42	Diagnostic Speciality Slides	X5ES242BAD1
43	Diagnostic Speciality Slides	X5ES248BAD1
44	Diagnostic Speciality Slides	X5XER201BAD1
45	Diagnostic Speciality Slides	X5XER202LCC2
46	Diagnostic Speciality Slides	X5XER202WAD1
47	Diagnostic Speciality Slides	X5XER203BAD1
48	Diagnostic Speciality Slides	X5XMZ231LCC2
49	Colorfrost Plus Slides	9991015
50	Colorfrost Plus Slides	9991014
51	Colorfrost Plus Slides	9991012
52	Colorfrost Plus Slides	9991011
53	Colorfrost Plus Slides	9991013
54	Colorfrost Plus Slides	9991009
55	Colorfrost Plus Slides	9991002
56	Colorfrost Plus Slides	9991004
57	Colorfrost Plus Slides	9991001
58	Colorfrost Plus Slides	9991003
59	Colormark Plus Slides	B9992010TN
60	Colormark Plus Slides	B9992010RD
61	Colormark Plus Slides	B9992010LV
62	Colormark Plus Slides	B9992010BO

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No.	Product Name	Product Number
63	Colormark Plus Slides	B9992010AQ
64	Colormark Plus Slides	B9992010PK
65	Colormark Plus Slides	B9992010GR
66	Colormark Plus Slides	B9992010GL
67	Colormark Plus Slides	B9992010BL
68	Colormark Plus Slides	B9992010
69	Colormark Plus Slides	B9992010YW
70	Colormark Slides	B9992010PKCSUNC
71	Cytoslide	5991056
72	DoubleCytoslide	5991055
73	Polysine Slides	6776216
74	Polysine Slides	6776215
75	Superfrost Plus Slides	6776214
76	Superfrost Plus Slides	9991000

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