EU Declaration of Conformity

TO IVD REGULATION (EU) 2017/746

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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.

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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:

Heather Gallacher
Director, Global Regulatory Affairs

Place of Issue: Scotland, UK

Date of Issue: 23 January 2024

Revision: 7.0

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

- **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 pink	J1820AMNZ
11	Superfrost Plus white	J1800AHTX
12	Superfrost Plus green	J1840AMNZ
13	Superfrost Plus white CC	J7800AMNZ
14	Polysine white	J2800ABDH
15	Superfrost Plus white	J1800AMNZTR
16	Superfrost Plus blue	J1810ABDH
17	Superfrost Excell white	J5800AMNZ
18	Superfrost Plus pink	J1820ABDH
19	Superfrost Plus yellow	J1830ABDH
20	Superfrost Plus green	J1840ABDH
21	Superfrost Plus orange CC	J7850AMNZ
22	Polysine white	J2800ARLX
23	Superfrost Plus blue	J1810ARLX
24	Superfrost Plus orange	J1850AMNZ
25	Superfrost Plus 51 x 75 mm	J1800BMNZ
26	Superfrost Plus yellow	J1830ARLX
27	Superfrost Plus green CC	J7840ARLX
28	Polysine white	J2800AHTX
29	Superfrost Plus green	J1840ARLX
30	Superfrost Plus pink	J1820ARLX

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No.	Product Name	Product Number
31	Superfrost Plus 38 x 75 mm	J1800CMNZ
32	Superfrost Plus orange	J1850ARLX
33	Superfrost Plus violet	J1860AMNZ
34	Capillary-gap Slidesgrau 75 µm	J6409741WGYPLUS
35	Capillary-gap Slidesblue 100 µm	J6815741WPLUS
36	Superfrost Plus GOLD white	K5800AMNZ72
37	SlideMate™ Plus Adhesion Microscope Slides White Tab	TT-40418218-PS-W
38	Diagnostic Speciality Slides	X5ES2030LAD1
39	Diagnostic Speciality Slides	X5ES2115BAD1
40	Diagnostic Speciality Slides	X5ES2165BAD1
41	Diagnostic Speciality Slides	X5ES242BAD1
42	Diagnostic Speciality Slides	X5ES248BAD1
43	Diagnostic Speciality Slides	X5XER201BAD1
44	Diagnostic Speciality Slides	X5XER202LCC2
45	Diagnostic Speciality Slides	X5XER202WAD1
46	Diagnostic Speciality Slides	X5XER203BAD1
47	Diagnostic Speciality Slides	X5XMZ231LCC2
48	Colorfrost Plus Slides	9991015
49	Colorfrost Plus Slides	9991014
50	Colorfrost Plus Slides	9991012
51	Colorfrost Plus Slides	9991011
52	Colorfrost Plus Slides	9991013
53	Colorfrost Plus Slides	9991009
54	Colorfrost Plus Slides	9991002
55	Colorfrost Plus Slides	9991004
56	Colorfrost Plus Slides	9991001
57	Colorfrost Plus Slides	9991003
58	Colormark Plus Slides	B9992010TN
59	Colormark Plus Slides	B9992010RD
60	Colormark Plus Slides	B9992010LV
61	Colormark Plus Slides	B9992010BO
62	Colormark Plus Slides	B9992010AQ

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No.	Product Name	Product Number
63	Colormark Plus Slides	B9992010PK
64	Colormark Plus Slides	B9992010GR
65	Colormark Plus Slides	B9992010GL
66	Colormark Plus Slides	B9992010BL
67	Colormark Plus Slides	B9992010
68	Colormark Plus Slides	B9992010YW
69	Colormark Slides	B9992010PKCSUNC
70	Cytoslide	5991056
71	DoubleCytoslide	5991055
72	Polysine Slides	6776216
73	Polysine Slides	6776215
74	Superfrost Plus Slides	6776214
75	Superfrost Plus Slides	9991000
76	Superfrost Plus™ white	J1800AAUT
77	SlideMate™ Plus Adhesion Microscope Slides Blue Tab	TT-50418218-PS-B
78	SlideMate™ Plus Adhesion Microscope Slides Green Tab	TT-60418218-PS-G
79	SlideMate™ Plus Adhesion Microscope Slides Pink Tab	TT-70418218-PS-P
80	SlideMate™ Plus Adhesion Microscope Slides Yellow Tab	TT-80418218-PS-Y
81.	SlideMate™ Laser Plus Microscope Slides White tab	LS-4041IPS8523-1CE
82	SlideMate™ Laser Plus Microscope Slides Blue tab	LS-5041IPS8523-1CE
83	SlideMate™ Laser Plus Microscope Slides Green tab	LS-6041IPS8523-1CE
84	SlideMate™ Laser Plus Microscope Slides Pink tab	LS-7041IPS8523-1CE
85	SlideMate™ Laser Plus Microscope Slides Yellow tab	LS-8041IPS8523-1CE