

# 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<br>(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.<br>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:

A handwritten signature in dark ink, appearing to read "H Gallacher", is written over a light grey signature line.

Heather Gallacher  
Director, Global Regulatory Affairs

Place of Issue: Scotland, UK

Date of Issue: 23 January 2024

Revision: 7.0

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## • 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<br>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 |

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