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 Trade Name	**Microscope Slide Coverslips**
Intended Purpose	Microscope slide coverslips are suitable for cellular and tissue specimen preparation for microscopic analysis intended for diagnostic use. Microscope slide coverslips serve as a physical barrier to protect the specimen from mechanical forces and environmental exposure.
Classification & Classification Rules	Class A, Rule 5, Indent (a) per EU IVDR 2017/746.
Conformity Assessment Route	In accordance with Article 17 and Annex IV of IVDR 2017/746
Product Number	See Appendix 1
Basic UDI-DI	081004133NES002MQ
Nomenclature	15687
Initial CE Release Date	Year 2000
Authorized Representative Name and Address	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

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

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:

Mark Ramser
Vice President, Quality & Regulatory

Place of Issue: Kalamazoo, US

Date of Issue: 25-November-2022

Revision: 4.0

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	SAP Sales item code
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Document Approvals

Approved Date: 30 Nov 2022

Approval Task Verdict: Approve	Tejal Warange, Regulatory Affairs Specialist (tejal.warange@epredia.com) Regulatory Approval 30-Nov-2022 15:06:26 GMT+0000

QA Approval Task Verdict: Approve	Candace Mason, (Candace.Mason@epredia.com) Quality Assurance Approval 30-Nov-2022 15:23:17 GMT+0000

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