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DECLARATION OF CONFORMITY

Legal Manufacturer's Name: Luminex Corporation
Legal Manufactures' Address:
12212 Technology Blvd
Austin, TX 78727
USA

Single Registration Number:
Not Yet Requested

Declares under our sole responsibility that the product

Basic UDI: 0840847xMAPSHEATH9T
Product Name: xMAP® Sheath Fluid PLUS
Code Number: 40-50035
Risk Class: Class A, IVDR based on Annex VIII Rule 5 (a)
GMDN: 56727

Basic UDI: 0840847xMAPSHEATH9T
Product Name: xMAP® Sheath Concentrate PLUS
Code Number: 40-50036
Risk Class: Class A, IVDR based on Annex VIII Rule 5 (a)
GMDN: 56727

meets all provisions of the Regulation 2017/746 on In Vitro diagnostic Medical Devices which apply to the product.

Applied Common Specifications:

Reference to the applied harmonized standards is listed in the Technical Documentation.

Conformity Assessment Procedure: IVD Regulations 2017/746, Annex IV

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Digitally signed by Talpiş Andrei
Date: 2024.07.05 11:24:58 EEST
Reason: MoldSign Signature
Location: Moldova

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Notified Body Details: Not applicable – Class A

EC Certificate Number: N/A

European Authorized Representative:
WMDE B.V
Bergerweg 18
6085 AT Horn
The Netherlands

Single Registration Number: NL-AR-000002062

Person keeping the Technical Documentation: 03934, CE Technical File for xMAP® Sheath Fluid PLUS and xMAP® Sheath Concentrate PLUS

Place and Date: Agile 06/01/2022, 89-30001-00-071 Rev. A

Tara Viviani
Sr. Director, Molecular Regulatory Affairs

Angelo Rago
President