

**DECLARATION OF CONFORMITY**

Legal Manufacturer's Name: Luminex Corporation

Single Registration Number:

Legal Manufactures' Address:

Not Yet Requested

12212 Technology Blvd

Austin, TX 78727

USA

**Declares under our sole responsibility that the product**

Basic UDI: 0840847xMAPSHEATH9T

Product Name: xMAP<sup>®</sup> 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<sup>®</sup> 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

Notified Body Details: Not applicable – Class A

EC Certificate Number: N/A

European Authorized Representative:

Single Registration Number: NL-AR-000002062

WMDE B.V

Bergerweg 18

6085 AT Horn

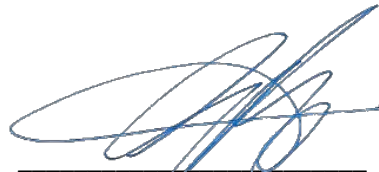
The Netherlands

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  
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Angelo Rago  
President