

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: 0840847FM3DCALVERDV

Product Name: FLEXMAP 3D[®] Calibration Kit

Code Number: F3DIVD-CAL-K25

Risk Class: Class A, IVDR based on Annex VIII Rule 5 (a)

GMDN: 56727

Basic UDI: 0840847FM3DCALVERDV

Product Name: FLEXMAP 3D[®] Performance Verification Kit

Code Number: F3DIVD-PVER-K25

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

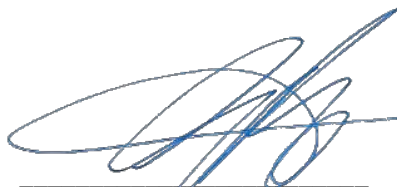
Person keeping the Technical Documentation: 03972, CE Technical File for FLEXMAP 3D® Calibration and Performance Verification Kits

Place and Date: Agile 06/15/2022, 89-30001-00-041 Rev A



Tara Viviani

Sr. Director, Molecular Regulatory Affairs



Angelo Rago

President