

## DECLARATION OF CONFORMITY

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

Single Registration Number:  
Not Available

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

Basic UDI: 0840847FM3DSYSTEMVJ

Product Name: FLEXMAP 3D® Instrument

Code Number: FLEXMAP-3D

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

GMDN: 56727

Basic UDI: 0840847FM3DSYSTEMVJ

Product Name: xPONENT® for FLEXMAP 3D software, version 4.3u1

Code Number: CN-SW64-02

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

GMDN: 43472

**meets all provisions of the Regulation 2017/746 on In Vitro diagnostic Medical Devices  
(and of RoHS Directive 2011/65/EU Art. 4, as applicable) which apply to the product.**

Applied Common Specifications: Not Applicable

**The applied harmonized standards are listed in the Technical Documentation  
04044, Section 001, Part 0, Administrative Information, Sub-section 0.12.  
Use of Harmonized Standards.**

Conformity Assessment Procedure: IVD Regulations 2017/746, Annex II-III

Luminex Corporation

A DiaSorin Company

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Notified Body Details: Not applicable – Class A

EC Certificate Number: N/A

European Authorized Representative:

Single Registration Number: Not Available

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Person keeping the Technical Documentation: 04044, CE Technical File for FLEXMAP® 3D Instrument and Software, Jennifer Svoboda, Sr. Manager, Regulatory Affairs, Phone +1 512-249-4784,

Place and Date Austin, Texas USA: Agile 09/06/2022, 89-30001-00-120 Rev B



Tara Viviani

Sr. Director, Molecular Regulatory Affairs




Angelo Rago

President

State of Wisconsin  
County of Waukesha

I certify that this is a true and correct copy of a document in the possession of Sateesh Kyasaram which was copied on February 12, 2024.

Notary



Notary's expiration date: March 28, 2025

