

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: 0840847LXCALVER9E

Product Name: Luminex[®] 100/200[®] Calibration Kit

Code Number: LX200-CAL-K25

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

GMDN: 56727

Basic UDI: 0840847LXCALVER9E

Product Name: Luminex[®] 100/200[®] Performance Verification Kit

Code Number: LX200-CON-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

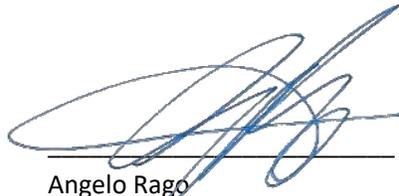
The Netherlands

Person keeping the Technical Documentation: 03935, CE Technical File for Luminex 100/200 Calibration Kit and Performance Verification Kit (IVDR)

Place and Date: Agile 06/21/2022, 89-30001-00-050, Rev. A



Tara Viviani
Sr. Director, Molecular Regulatory Affairs



Angelo Rago
President