Luminex

Declaration of Conformity

Device Identification: FLEXMAP 3D®

Device Description: The Luminex® FLEXMAP 3D® system with xPONENT® software is a clinical multiplex test system intended to measure and sort multiple signals generated in an *in vitro* diagnostic assay from a clinical sample. This instrumentation is intended for use with specific IVD cleared or approved assays citing its use, to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The system includes the components listed in the Device Components table below.

Classification: General IVD

Device Components*:

Hardware:	Description	Format	Catalog Number
FLEXMAP 3D® instrument	The instrument component acquires and analyzes the samples.	1 unit	FLEXMAP-3D
Software:			
xPONENT® for FLEXMAP 3D software, version 4.0 SP1	The software is used to control the system, set up tests, and perform data analysis. Note: Kit manufacturers may provide their own analysis component software.	DVD	CN-SW16-01
xPONENT® for FLEXMAP 3D software, version 4.2	The software is used to control the system, set up tests, and perform data analysis. Note: Kit manufacturers may provide their own analysis component software.	DVD	CN-SW37-01
xPONENT® for FLEXMAP 3D software, version 4.2 Patch 1920	The software is used to control the system, set up tests, and perform data analysis. Note: Kit manufacturers may provide their own analysis component software.	DVD	CN-SW37-02
xPONENT® for FLEXMAP 3D software, version 4.3	The software is used to control the system, set up tests, and perform data analysis. Note: Kit manufacturers may provide their own analysis component software.	DVD	CN-SW64-01
Reagents:**			
FLEXMAP 3D® Calibration Kit	Bottles of internally dyed microspheres used to normalize the settings for the classification and reporter channels of the FLEXMAP 3D instrument.	25 use kit	F3DIVD-CAL-K25
FLEXMAP 3D® Performance Verification Kit	Bottles of internally dyed microspheres in various mixtures used to verify the calibration status and integrity of the optical and fluidic pathways relevant to the classification and reporter channels of the FLEXMAP 3D instrument.	25 use kit	F3DIVD-PVER-K25
xMAP® Sheath Fluid	Serves as the delivery medium to carry the sample to the optics component of the FLEXMAP 3D®.	20 L	40-50000
xMAP® Sheath Fluid PLUS	Serves as the delivery medium to carry the sample to the optics component of the FLEXMAP 3D®.	20 L	40-50035
xMAP® Sheath Concentrate Pack	Once diluted to working concentration, serves as the delivery medium to carry the sample to the optics component of the FLEXMAP 3D®.	1 L	40-75680
xMAP® Sheath Concentrate PLUS	Once diluted to working concentration, serves as the delivery medium to carry the sample to the optics component of the FLEXMAP 3D®.	1 L	40-50036

*Items may be shipped as a whole system or as individual components, therefore, this declaration of conformity must be read in conjunction with the invoice.

** xMAP® Sheath Fluid (40-50000), xMAP® Sheath Fluid PLUS (40-50035), xMAP® Sheath Concentrate Pack (40-75680), and xMAP® Sheath Concentrate PLUS (40-50036) reagents are also used with and included in the notification for the Luminex® 100/200™ instrument.

Luminex®

Manufacturer:	Luminex Corporation 12212 Technology Blvd Austin, TX 78727 United States of America	**European Union (EU) Authorized Representative:** *Formally WMDE	Winckels Medical Devices Expertise WMDE B.V.* Bergerweg 18 6085 AT Horn The Netherlands

EU Country: The Netherlands

Notified Body: Not applicable (self-declaration)

Means of Conformity:

The undersigned declares that this product is designed, developed, and manufactured according to EN ISO 13485:2016, and fulfills the obligations imposed by "Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices" in accordance with Annex I: Essential Requirements and Annex III: EC Declaration of Conformity (Section 6 is not applicable).

Wendy Ricker (Director, Regulatory Affairs) — Date: 11/2/20

CE

Applicable Tested Standards:

Electromagnetic compatibility (EMC):

- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements – Part 1: Generic requirements
- EN 61326-2-6:2013 / IEC 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Safety:

- IEC 61010-1:2010 / EN 61010-1:2010 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
    - IEC 61010-2-081:2015 / EN 61010-2-081:2015 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
    - IEC 61010-2-010:2014 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
    - IEC 61010-2-101:2015 / EN 61010-2-101:2015 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
    - IEC 60825–1:2014 / EN 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
    - US CDRH 21 CFR 1040.10 and 1040.11 as a Class I laser product (total system), optional bar code scanner is a Class II stand-alone component
    - Compliance with national differences: IEC and CENELEC member countries as listed in the online CB bulletin, as well as Australia, New Zealand, Japan, Korea, USA, and Canada deviations.

The FLEXMAP 3D system was designed and is manufactured in accordance and is compliant with the following applicable standards and regulations:

- EN ISO 13485:2016 under MDSAP - Quality Management Systems: Medical Devices-System
- EN ISO 14971:2012 Medical Devices: Application of Risk Management to Medical Devices
- EU In-Vitro Diagnostics Directive (98/79/EC)
- EU Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU)
- US FDA 21CFR 820
- Regulation (EC) No 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- EU Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU)
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EU Low Voltage Directive (LVD) 2006/95/EC
- EN 62304:2006+A1:2015 - Medical Device Software – Software life cycle processes

- EN ISO 23640:2015 Stability Testing of In Vitro Diagnostic Reagents
- EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices
- IEC 60068-2-27:2009 - Basic Environmental Testing Procedures Part 2: Tests - Test Ea and Guidance: Shock
- IEC 60068-2-6:2008 - Environmental Testing Procedures Part 2: Tests - Test Fc: vibration (Sinusoidal)
- ISO 18113-1:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements
- ISO 18113-2:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use
- ISO 18113-3:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use
- Canadian Medical Device Regulations
- Directive 1999/45/EC
- Directive 67/548/EEC
- Directive 2004/108/EC
- Directive 94/62/EC (Packaging and packaging waste)
- IECEE CB Scheme