

Luminex®

Declaration of Conformity

Device Identification: Luminex® 100/200™ System

Device Description: The Luminex system is a multiplex test system intended to measure and sort multiple signals generated in an assay from a sample. The system includes the components listed in the Device Components table below.

Classification: General IVD

Device Components¹:

| Hardware: | Description | Format | Catalog No. |
|--|---|------------|----------------|
| Luminex® 100/200™ System contains the following components: | | | |
| Luminex® 100/200™ | Instrument component that acquires and analyzes the samples. May also be labeled as Luminex® 200™. Includes the Luminex® XYP™, Luminex® SD™ and xPONENT software. | 1 unit | LX200-XPON-IVD |
| | Instrument component that acquires and analyzes the samples. May also be labeled as Luminex® 200™. Includes the Luminex® XYP™, Luminex® SD™, and xPONENT 3.1 software. | | LX200-XPON3.1 |
| xMAP® Sheath Fluid ² | Serves as the delivery medium to carry the sample to the optics component of the Luminex® 100/200™. | 20 L | 40-50000 |
| xMAP® Sheath Fluid PLUS ² | Serves as the delivery medium to carry the sample to the optics component of the Luminex® 100/200™. | 20 L | 40-50035 |
| xMAP® Sheath Concentrate Pack ² | Once diluted to working concentration, serves as the delivery medium to carry the sample to the optics component of the Luminex® 100/200™. | 1 L | 40-75680 |
| xMAP® Sheath Concentrate PLUS ² | Once diluted to working concentration, serves as the delivery medium to carry the sample to the optics component of the Luminex® 100/200™. | 1 L | 40-50036 |
| Software: | | | |
| xPONENT® 3.1 Rev. 2 | Software used to control the system, set up tests, and to perform data analysis. Note: Kit manufacturers may provide their own analysis component software. | DVD | CN-SW23-01 |
| xPONENT 4.2® for LX100/200 | Software used to control the system, set up tests, and to perform data analysis. Note: Kit manufacturers may provide their own analysis component software. | DVD | CN-SW53-01 |
| xPONENT 4.3® for LX100/200 | Software used to control the system, set up tests, and to perform data analysis. Note: Kit manufacturers may provide their own analysis component software. | DVD | CN-SW63-01 |
| xMAP Reagents with IS 2.3 | | | |
| xMAP® Classification Calibrator | Internally dyed microspheres used to normalize the settings for the 3 classification channels of the Luminex 100/200. | 5.0 mL | L100-CAL1 |
| xMAP® Reporter Calibrator | Internally dyed microspheres used to normalize the settings for the single reporter channel of the Luminex 100/200. | 5.0 mL | L100-CAL2 |
| xMAP® Classification Control | Internally dyed microsphere mix used to verify calibration status and integrity of the optical pathways relevant to the 3 classification channels of the Luminex 100/200. | 5.0 mL | L100-CON1 |
| xMAP® Reporter Control | Internally dyed microsphere mix used to verify calibration status and integrity of the optical pathways relevant to the reporter channel of the Luminex 100/200. | 5.0 mL | L100-CON2 |
| xMAP Reagents with xPONENT | | | |
| Luminex 100/200® Calibration Kit | Bottles of internally dyed microspheres used to normalize the settings for the classification and reporter channels of the Luminex 100/200 instrument. | 25 use kit | LX200-CAL-K25 |
| Luminex 100/200® Performance Verification Kit | Bottles of internally dyed microspheres in various mixtures used to verify calibration status and integrity of the optical and fluidic pathways relevant to the classification and reporter channels of the Luminex 100/200 instrument. | 25 use kit | LX200-CON-K25 |

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¹Items may be shipped as a whole system or as individual components; therefore, this declaration of conformity must be read in conjunction with the invoice.

² 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 FLEXMAP 3D®.

Manufacturer: Luminex Corporation
12212 Technology Blvd
Austin, Texas, 78727
United States of America

European Union (EU) Authorized Representative: Winckels Medical Devices Expertise
WMDE B.V.*
Bergerweg 18
6085 AT Horn
The Netherlands

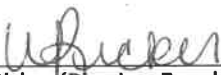
*Formally WMDE

EU Country: The Netherlands

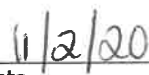
Notified Body: Not applicable (self-declaration)

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



The Luminex 100/200 system was tested and found to be in compliance with:

Electromagnetic compatibility (EMC):

- BS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements – Part 1: Generic requirements
- BS EN 61326-2-6:2013 Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- EN 61000-6-3:2007+A1:2011 Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments
- FCC 47 CFR Part 15, Subpart B, Class B– Radio Frequency Devices Subpart B - Unintentional Radiators
- ICES 003:2004– Digital Apparatus - Spectrum Management and Telecommunications Policy Interference-Causing Equipment Standard

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 61010-2-010:2014 / BS EN 61010-2-010:2014 Part 2-010: Particular requirements for laboratory equipment for the heating of materials
 - IEC 61010-2-081:2015 / BS EN 61010-2-081:2015 Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
 - IEC 61010-2-101:2015 Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
 - BS EN 61010-2-101:2015 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 standalone Class II 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.
- UL 61010-1:2012 (Third edition) Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- CSA C22.2 No. 61010-1:2012 (Third edition) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

The Luminex 100/200 system was designed and is manufactured in accordance with the following standards and regulations:

- EN ISO 13485:2016 under MDSAP - Quality Management Systems: Medical Devices-System
- ISO 14971:2012 Medical Devices: Application of Risk Management to Medical Devices

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- EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 23640:2013 Evaluation of stability of in vitro diagnostic reagents
- EN 62304:2006+A1:2015 - Medical Device Software – Software life cycle processes
- EU Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU)
- EU Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU)
- 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
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements