Luminex®

Declaration of Conformity

Device Family: VERIGENE® Instruments System

Device Description: The VERIGENE® Instruments System is an in vitro diagnostic device intended for processing and genotyping multiple genes in a DNA sample utilizing gold nanoparticle probe technology. The VERIGENE® Instruments System consists of the Verigene Processor and the Verigene Reader, each with its own onboard proprietary software. The VERIGENE® Instruments System is intended to be used by experienced laboratory professionals with training on basic laboratory techniques and on the use of the system components. The system includes the components listed in the Device Components table below.

Classification: General IVD

Device Identification:

Hardware	Format	Catalog Number
VERIGENE Reader	1 unit	10-0000-02
VERIGENE Processor SP	1 unit	10-0000-07

Manufacturer: Luminex Corporation
4088 Commercial Ave.,
Northbrook, IL 60062, USA
United States of America

European Union (EU) Authorized Representative According to the IVD Directive 98/79/EC: QARAD EC-REP b.v.b.a
Pas 257
B-2440 Geel
Belgium

EU Country: Belgium

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), and fulfills the obligations imposed by Directive 2011/65/EU.

W Ricker
Wendy Ricker (Director, Regulatory Affairs)

12/3/2019
Date

CE

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The VERIGENE® Instruments System was tested and found to be in compliance with:

Electromagnetic compatibility (EMC):

- EN 61326-1:2013 / IEC 61326-1:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements - CORR: October 31, 2013
- EN 61326-2-6:2013 / IEC 61326-2-6:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- EN 61000-3-2:2014 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions, Input Current Up To & Including 16A Per Phase
- EN 61000-3-3:2013 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems for equipment with rated current <= 16 A

Safety:

- IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 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

The VERIGENE® Instruments System was designed and is manufactured in accordance with the following standards and regulations:

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