Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester
New York 14626
USA

Manufacturing and Refurbishment Facility:

NPA de Mexico S. de R.L de C.V.
Sor Juana Ines de la Cruz # 20150 Interior 5
Cd. Industrial
Tijuana Baja California, MEXICO 22444

Authorized Representative:

Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335
67411 Illkirch
CEDEX, France

Declaration of Conformity – Directive 98/79/EC

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618 and the French Ordinance No. 2001-198 of March 2001. The manufacturer has the sole responsibility for issuance of the declaration of conformity and all supporting documentation is retained under their control.

Product Name:	**Product Code:**
VITROS 3600 Immunodiagnostic System	6802783
VITROS 3600 Immunodiagnostic System Refurbished	6802914

DECLARATION OF CONFORMITY *(continued)*

Classification: Non-Annex II / General / GIVD (other)

Conformity Assessment Route: Annex III

STANDARDS APPLIED:

- EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-3:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 3: Instruments for professional use
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- BS EN 62304:2006+A1:2015 Medical device software. Software life-cycle processes
- EN 61326-1:2006 (IEC 61326-1:2005) Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General Requirements
- EN 61326-2-6:2006 (IEC 61326-2-6:2005) Electrical equipment for measurement, control, and laboratory use-EMC requirements - Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- EN/IEC 61010-1: 2010 (3rd Edition) Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements*
- EN/IEC 61010-2-010:2014 (3rd Edition) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for laboratory equipment for the heating of Materials*
- EN/IEC 61010-2-101:2015 (2nd Edition) Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment*

**Applies to instruments manufactured on or after 26 July 2017 - Systems manufactured before 26 July 2017 conform to IEC 61010-1 (ed.2), ANSI/UL 61010-1 (ed.2) and IEC 61010-2-101 (ed.1). Certified to CAN/CSA C22.2 No. 61010-1 (ed.2)*

Date of original CE-marking: 2008-11-20

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DECLARATION OF CONFORMITY *(continued)*

Declaration of Conformity – Directive 2011/65/EU and amended directive (EU) 2015/863

Based upon information made known to Ortho Clinical Diagnostics by our suppliers and our own investigations, we hereby declare that the products listed below comply with the substance requirements of Article 4 of the RoHS Directive 2011/65/EU, and *DO NOT* contain the ten restricted substances listed in Annex II as amended by the Commission Delegated Directive (EU) 2015/863 from March 31, 2015, in concentrations greater than the specified maximum concentration except for certain exemptions granted in Annex III or IV of this Directive.

Product Name:	**Product Code:**
VITROS 3600 Immunodiagnostic System	6802783
VITROS 3600 Immunodiagnostic System Refurbished	6802914

Compliance to Directive 2011/65/EU applies to Serial Number 36000953 and Above

Compliance to amended Directive (EU) 2015/863 applies to Serial Number 36001486 and Above

STANDARDS APPLIED:

- IEC 63000:2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
- EN/IEC 62321:2009 Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, Hexavalent chromium, Polybrominated biphenyls, Polybrominated diphenyl ethers).

Digitally signed by Maftei Tatiana
Date: 2022.10.13 12:27:05 EEST
Reason: MoldSign Signature
Location: Moldova

Samy Puccio

2022/05/16

Samy Puccio
Rochester, New York, USA
Director, Regulatory Affairs

Date: (year-month-day)