

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Declaration of Conformity – Directive 98/79/EC

Ortho-ClinicalDiagnostics is declaring that the *in vitro* diagnostic medical devices listed above comply with the provisions of Directive 98/79/EC on *in Vitro* Diagnostic Medical Devices, 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.

Manufacturer: Ortho-Clinical Diagnostics
Felindre Meadows,
Pencoed
Bridgend
CF35 5PZ
United Kingdom

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

Contract Manufacturer: TECAN Schweiz AG
Seestrasse 103
CH-8708 Männedorf
Switzerland

Product Name	Product Code
ORTHO VISION® Analyzer	6904579
ORTHO VISION® Analyzer Refurbished	6174455

Accessory Name	Code	Physical Manufacturer
ORTHO VISION Evaporation Caps (3mL)	6843004	Tessy Plastics 488 Route 5 W Elbridge, NY 13060 USA
ORTHO VISION Evaporation Caps (10mL)	6843005	G. W. Plastics, Inc. 272 Waterman Road South Royalton, VT 05068 USA
ORTHO VISION Dilution Tray	6904591	Alltrista Plastics Limited Unit 3, 81 Somerford Road Christchurch, Dorset, BH23 3PP, United Kingdom

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

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY (*continued*)

STANDARDS APPLIED:

- EN ISO 13485: 2016 Medical devices – Quality Management Systems-Requirements for Regulatory Purposes
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971:2019 Medical devices – Application of risk management to medical devices
- 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
- 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 (labelling) – Part 3: In vitro diagnostic instruments for professional use
- IEC 61010-1: 2001 Safety requirements for electrical equipment for measurement, control and laboratory use
- IEC 61010-2-010:2003 Particular requirements for laboratory equipment for the heating of materials
- IEC 61010-2-020:2006 Particular requirements for laboratory centrifuges.
- IEC 61010-2-081:2001 Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- IEC 61010-2-101:2002 Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-1:2013 (IEC 61326-1): Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General Requirements
- 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 62304:2006 Medical Device Software-Software Life Cycle Processes
- EN 62366:2008 (ANSI/AAMC/IEC 62366:2007) Medical Devices – Application of usability engineering to medical devices

Conformity Assessment Route: Annex III

Date of Original CE marking: 27 October 2014

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

Declaration of Conformity – Directive 2011/65/EU & 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: ORTHO VISION® Analyzer
Product Code: 6904579

Compliance to Directive 2011/65/EU applies to Serial Number SN 60002300 and above.

Compliance to amended Directive (EU) 2015/863 applies to Serial Number 60005040 and above.

Product Name: ORTHO VISION® Analyzer Refurbished
Product Code: 6174455

Compliance to Directive 2011/65/EU and amended Directive (EU) 2015/863 applies to all Serial Numbers.

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).



Name: Richard Saunders
Title: Technical Director, International Regulatory Affairs
Place: Pencoed, UK

2022/05/25
Date: (year/month/day)