Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Ortho-Clinical Diagnostics 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.

Manufacturer:
Ortho-Clinical Diagnostics
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP
United Kingdom

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

Product Name: ORTHO VISION™ Analyzer

Product Code: 6904579

Classification: Non-Annex II

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 62366:2008 Medical Devices – Application of usability engineering to medical devices
- EN 62304:2006 Medical Device Software-Software Life Cycle Processes
- 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
- EN ISO 15223-1:2012 Symbols to be used with medical device labels, labelling and information to be supplied
- EN ISO 13485: 2012 Medical devices – Quality Management Systems-Requirements for Regulatory Purposes (ISO 13485:2003)

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DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*:

- 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 61010-2-101:2002 Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61010-2-081:2001 Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- 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

Conformity Assessment Route: Annex III

Date of Original CE marking: 27 October 2014

Name: Richard Saunders
Place: High Wycombe, UK
Title: Senior Manager, International Regulatory Affairs

2015/02/23
Date: (year/month/day)