Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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

Authorized Representative:

Ortho-Clinical Diagnostics
Felindre Meadows
Pencoed
Bridgend CF35 5PZ
United Kingdom
Or
Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant,
B.P. 30335,
67411 Illkirch,
CEDEX, France

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.

Product Name: VITROS Chemistry Products 7% BSA

Product Code: 826 2487

Classification: Non-Annex II

Conformity Assessment Route: Annex III

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DECLARATION OF CONFORMITY *(continued)*

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 23640:2015 In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to 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 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents 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
- EN ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2003-06-17

Paul Goodacre
Rochester, New York, USA
Head of Quality, Regulatory & Compliance

2019-July-08
Date: (year-month-day)