

Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics is declaring that the *in vitro* diagnostic medical devices listed below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices, the UK Medical Devices Regulations 2002, No: 618, 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.

DECLARATION OF CONFORMITY

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

MANUFACTURING FACILITY: Ortho-Clinical Diagnostics
Felindre Meadows
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EC AUTHORISED REPRESENTATIVE: Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335, 67411 Illkirch
CEDEX, France

PRODUCT: Ortho BioVue® System Anti-Human Globulin Reagents

Product Codes	Abbreviated Name	Product Name
707450, 707400	IgG Cassette	Anti-Human Globulin Anti-IgG (Rabbit) (Green) Ortho BioVue® System (IgG Cassette)
707350, 707300	Poly Cassette	Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Rabbit and Murine Monoclonal) (Green) Ortho BioVue® System (Poly Cassette)

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Product Codes	Abbreviated Name	Product Name
707355, 707310	Poly/Neutral Cassette	Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Rabbit and Murine Monoclonal) (Green) Neutral Solution Ortho BioVue® System (Poly/Neutral Cassette)
707165	DAT/IDAT Cassette	Anti-Human Globulin Anti-IgG (Rabbit) Anti-Human Globulin Anti-C3b, -C3d (Monoclonal) Control Ortho BioVue® System (DAT/IDAT Cassette)
707650, 707680	Neutral Cassette	Neutral Ortho BioVue® System (Neutral Cassette)

CLASSIFICATION:

Annex II List B

CONFORMITY ASSESSMENT

ROUTE:

Annex IV

STANDARDS APPLIED:

- EN ISO 14971:2012 Medical devices – Application of risk management to 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 reagents
- 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 (labelling) - Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
- EN ISO 15223-1:2016 Symbols for use in the labelling of medical devices
- EN ISO 13485: 2016 - Medical devices. Quality management systems. Requirements for regulatory purposes.
- EN ISO 62366-1 Medical Devices – Part 1: Application of usability engineering to medical devices

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NOTIFIED BODY: TÜV SÜD Product Service GmbH
Zertifizierstelle
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80339 München
Germany

NOTIFIED BODY NUMBER: 0123

DATE OF ORIGINAL CE-MARKING: July 2002

EC CERTIFICATE: V1 071279 0041 Rev. 02

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

2022/04/08

Date: (year/month/day)