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 and commission decision 2009/886/EC of 27 November 2009 on Common Technical Specifications for In-Vitro Diagnostic Medical Devices. 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 Pencoed Bridgend CF35 5PZ United Kingdom
EC AUTHORISED REPRESENTATIVE:	Ortho-Clinical Diagnostics 1500 Boulevard Sébastien Brant B.P. 30335, 67411 Illkirch CEDEX, France
PRODUCT:	Ortho BioVue® System Blood Grouping Reagents:

Product Code (s)	Abbreviated Name	Product Name
707150, 707190	ABO-Rh Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-CDE (Anti-RH1,2,3) (Monoclonal) Control Ortho BioVue® System (ABO-Rh Grouping Cassette)
707250, 707280	Rh/K Cassette	Blood Grouping Reagents Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti-c̄ (Anti-RH4) (Monoclonal) Anti-e (Anti-RH5) (Monoclonal) Anti-K (Anti-K1) (Monoclonal) Control Ortho BioVue® System (Rh/K Cassette)
707255	Rh-hr Cassette	Blood Grouping Reagents Anti-D (Anti-RH1) (Monoclonal) Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti-c̄ (Anti-RH4) (Monoclonal) Anti-e (Anti-RH5) (Monoclonal) Control Ortho BioVue® System (Rh-hr Cassette)
707100, 707155	ABO-Rh/Reverse Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette)
707135	ABD Confirmation Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Ortho BioVue® System (ABD Confirmation Casscttc)
6904485	ABD Confirmation Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Ortho BioVue® System (ABD Confirmation Cassette)

Product Code (s)	Abbreviated Name	Product Name
6901906	Newborn Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Anti-Human Globulin Anti-IgG (Rabbit) (Green) Ortho BioVue® System (Newborn Cassette)
707270	ADK Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-K (Anti-K1) (Monoclonal) Control Ortho BioVue® System (ADK Cassette)
707550, 707580	Reverse Diluent Cassette	Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette)
707119	ABO-DD Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Ortho BioVue® System (ABO-DD Grouping Cassette)
707117	K Cassette	Blood Grouping Reagent Anti-K (Anti-K1) (Monoclonal) Ortho BioVue® System (K Cassette)
6986736	ABD/Reverse Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Reverse Diluent Ortho BioVue® System (ABD/Reverse Cassette)

CLASSIFICATION: Annex II List A

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
- BS 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 ISO 13485: 2016 - Medical devices – Quality management systems - Requirements for regulatory purposes.

NOTIFIED BODY: TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65
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Germany

NOTIFIED BODY NUMBER: 0123

DATE OF ORIGINAL CE-MARKING: July 2002

EC DESIGN EXAMINATION CERTIFICATE: V7 071279 0046 Rev. 02

EC CERTIFICATE: V1 071279 0041 Rev. 02

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

Date: (year/month/day) 2022/04/07