



EC DECLARATION OF CONFORMITY

Product Name: ORTHO CONFIDENCE™ WB Simulated Whole Blood Quality Control Kit
Product Code: Z484
Legal Manufacturer: Alba Bioscience Limited
Address: James Hamilton Way, Penicuik, EH26 0BF, United Kingdom
Distributor: Ortho Clinical Diagnostics, Inc.
Distributor Product Code: 6842785
EC Authorised Representative: Emergo Europe B.V.
EC Authorised Representative Address: Prinsessegracht 20
2514 AP The Hague
The Netherlands

This declaration of conformity is issued under the sole responsibility of the manufacturer. The product described above complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *In Vitro* Diagnostic Medical Devices.

Conformity Assessment Procedure:

Directive(s)	Annex(es)	Classification
98/79/EC	Annex IV section 4 & 6 included	Annex II List A

This Directive is transposed into UK legislation in: Statutory Instrument 2002 No. 618 - The Medical Devices Regulations 2002, as amended by the Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (UK MDR 2019).

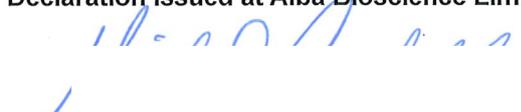
List of Harmonized Standard(s):

- BS EN ISO 13485 Quality management systems, medical devices – system requirements for regulatory purposes.
- BS EN 13612 Performance evaluation of *in vitro* diagnostic medical devices.
- BS EN ISO 23640 *in vitro* diagnostic medical devices. Evaluation of stability of *in vitro* diagnostic reagents.
- BS EN ISO 14971 Medical devices – Application of risk management to medical devices.
- BS EN ISO 18113-1 *in vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements.
- BS EN ISO 18113-2 *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 medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

Identification of Notified Body certificate(s):

Name of Notified Body: Polish Centre for Testing and Certification (CE 1434)
Certificate(s) number: Full Quality Assurance: 1434-IVDD-121/2022
Design Examination: 1434-IVDD-120/2022

Declaration issued at Alba Bioscience Limited, Edinburgh, UK on 07 June, 2022


Michael Campbell
Head of Regulatory Affairs & Quality, Member of Executive Team