

## EC Declaration of Conformity

**No:** FD039B/06  
**Manufacturer** Alba Bioscience Limited  
**Address:** James Hamilton Way, Penicuik, EH26 0BF, United Kingdom  
**Product Name:** ORTHO™ Sera Anti-D (DVI) Human Monoclonal IgM  
for Ortho BioVue® System (CAT)  
**Product Code:** FD039B  
**Distributor:** Ortho Clinical Diagnostics, Inc.  
**OCD Product Code:** 6904623

**This declaration of conformity is issued under the sole responsibility of the manufacturer. Using conformity assessment route Annex IV (Full Quality Assurance System) for Annex II, List A devices, the product described above is in conformity with:**

<b>Document No.</b>	<b>Title</b>	<b>Edition/Date of Issue</b>
98/79/EC	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON <i>IN VITRO</i> DIAGNOSTIC MEDICAL DEVICES.	27 October 1998

**This Directive is transposed into UK legislation in:** Statutory Instrument 2002 No. 618 - The Medical Devices Regulations 2002, which came into force on 13<sup>th</sup> June 2002.

### **List 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.

The Notified Body UL International (UK) Ltd. (CE 0843) performed examination of the design of the product and issued the following certificate(s):

**Certificate Number(s):** 677.181030

### **Additional information**

The product described above also complies with the recommendations contained in the “Guidelines for the Blood Transfusion Services in the United Kingdom”.

**Issued at Alba Bioscience Limited, Edinburgh on 25 October 2018**

  
**Robert Dorris, Executive Vice President, Quality**