

## **EC Declaration of Conformity**

**No:** FD041B/02

**Manufacturer:** Alba Bioscience Limited

**Address:** Ellen's Glen Road, Edinburgh, EH17 7QT

**Product Name:** ORTHO™ Sera Anti-D (IAT), Human Monoclonal IgM/IgG for Ortho BioVue® System (CAT)

**Product Code:** FD041B

**Distributor:** Ortho Clinical Diagnostics, Inc.

**OCD Product Code:** 6904493

**Using conformity assessment route: Annex IV (Full Quality Assurance System), for an Annex II, List A device. The product described above is in conformity with:**

Document No.	Title	Edition/Date of Issue
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.**

### **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, Edinburgh on 04 November 2013**

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**Robert Dorris**  
**Quality Assurance and Regulatory Affairs Director**