

EC Declaration of Conformity

No: FD166B/02
Manufacturer: Alba Bioscience Limited
Address: Ellen's Glen Road, Edinburgh, EH17 7QT
Product Name: ORTHO™ Sera Anti-Jk^b Human Monoclonal IgM for Ortho BioVue® System (CAT)
Product Code: FD166B
Distributor: Ortho Clinical Diagnostics, Inc.
OCD Product Code: 6904489

Using conformity assessment route: Annex IV (Full Quality Assurance System), for an Annex II, List B 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 13th 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


04 Nov 13

Robert Dorris
Quality Assurance and Regulatory Affairs Director