Ortho-Clinical Diagnostics
a Johnson & Johnson company
1001 US HWY 202
Raritan, NJ 08869-0606

DECLARATION OF CONFORMITY

MANUFACTURER:	Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869-0606 U.S.A.
AUTHORIZED REPRESENTATIVE:	Ortho-Clinical Diagnostics Mandeville House 62 The Broadway Amersham Buckinghamshire HP7 0HJ United Kingdom Attention: Dr. Stephen Abbott
PRODUCT:	Anti-Kell (KEL1) Monoclonal IgM (Human) BioClone®
CLASSIFICATION:	Annex II List A
CONFORMITY ASSESSMENT ROUTE:	Annex IV

Ortho-Clinical Diagnostics, Inc. hereby declares Anti-Kell (KEL1) Monoclonal IgM (Human) BioClone® meets the provisions of the Council Directive 98/79/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

- EN 1441: October 1997 Medical Devices – Risk Analysis
- ISO 14971: 2000 (E) Medical devices – Application of risk management to medical devices
- EN 13640: March 2002 Stability testing of in vitro diagnostic reagents
- EN 13641: 2002 Elimination or reduction of risk of infection related to in vitro diagnostic medical devices

DECLARATION OF CONFORMITY (continued)

- Continuation Record 1 – Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
  EN 13612: December 2002 Performance evaluation of in vitro diagnostic medical devices
- EN 12740: July 1999 Biotechnology – Laboratories for research, development and analysis – Guidance for handling, inactivating and testing of waste
- EN 375: January 2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- EN 980: August 2002 Graphical symbols for use in the labeling of medical devices
- ISO 9001:1994 Quality Systems
- ISO 13485:1996 Quality Systems – Medical Devices
- EN 46001:1996 Quality Systems – Medical Devices

NOTIFIED BODY:

TÜV Product Service GmbH
Nichtaktive Medizinprodukte
Ridlerstr. 65
80339 Munchen
Germany

EC DESIGN EXAMINATION CERTIFICATE: **V7 03 08 20533 024**

EC CERTIFICATE: **V1 02 07 20533 005**

PLACE, DATE OF ISSUE: Raritan, NJ, U.S.A., 2003-08-28
Date

SIGNATURE:

Mizanu Kebede
Executive Director,
Quality, Regulatory, Compliance