



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  
62 The Broadway  
Amersham, Bucks, UK

**PRODUCT:** Ortho® BLISS

**CLASSIFICATION:** Non-annex II

**CONFORMITY ASSESSMENT  
ROUTE:** Annex III

Ortho-Clinical Diagnostics, Inc. hereby declares Ortho® BLISS 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: April 2003 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

**PLACE, DATE OF ISSUE:**

Raritan, NJ, U.S.A., 10/16/03  
Date

**SIGNATURE:**

  
Mizanu Kebede  
Executive Director,  
Quality, Regulatory, Compliance