



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[®] ProControl S1/S2 and
Ortho[®] ProControl E1/E2

CLASSIFICATION: Non-annex II

**CONFORMITY ASSESSMENT
ROUTE:** Annex IV

Ortho-Clinical Diagnostics, Inc. hereby declares Ortho[®] ProControl S1 and S2 and Ortho[®] ProControl E1 and E2 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: May 2002 Elimination or reduction of risk of infection related to in vitro diagnostic medical devices

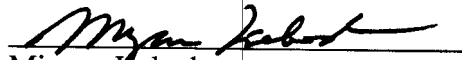
DECLARATION OF CONFORMITY (continued)

- 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 labeling of dangerous preparations.
- 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., 2003-10-21
Date

SIGNATURE:


Mizanu Kebede
Executive Director,
Quality, Regulatory, Compliance