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:

Affirmagen®
Affirmagen® 4
Ortho A_2 Cells

CLASSIFICATION: Annex II List A

CONFORMITY ASSESSMENT ROUTE: Annex IV

Ortho-Clinical Diagnostics, Inc. hereby declares Affirmagen, Affirmagen 4 and Ortho A_2 Cells meet 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
- prEN 13612: August 2000 Performance evaluation of in vitro diagnostic medical devices
- prEN 13640: April 2000 Stability testing of in vitro diagnostic reagents
- 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.

DECLARATION OF CONFORMITY (continued)

- prEN 13641: September 2000 Elimination or reduction of risk of infection related to 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: January 2001 Graphical symbols for use in the labelling of medical devices
- ISO 14971: 2000 Medical devices – Application of risk management to medical devices
- EN ISO 9001: 1994 Quality Systems
- EN 46001: 1996 Quality systems – Medical devices – Particular requirements for the application of EN ISO 9001
- ISO 13485: 1996 Quality systems – Medical devices – Supplementary requirements to ISO 9001

NOTIFIED BODY:

TÜV Product Service GmbH
Nichtaktive Medizinprodukte
Ridlerstr. 65
80339 Munchen
Germany
Identification No. 0123

EC DESIGN EXAMINATION CERTIFICATE:

V7 02 12 20533 011

EC CERTIFICATE:

V1 02 07 20533 005

PLACE, DATE OF ISSUE:

Raritan, NJ, U.S.A., 2003-05-16

SIGNATURE:

Mizanu Kebede
Executive Director,
Quality, Regulatory, Compliance