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

PRODUCTS:

Anti-A/Anti-B/Anti-A,B/Anti-D/Anti-CDE/Control Ortho BioVue® System (ABO-Rh Grouping Cassette)
Anti-C/Anti-E/Anti-c/Anti-e/Anti-K/Control Ortho BioVue® System (Rh/K Cassette)
Anti-D/Anti-C/Anti-E/Anti-c/Anti-e/Control Ortho BioVue® System (Rh-hr Cassette)
Anti-A/Anti-B/Anti-D/Control/Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette)
Anti-A/Anti-B/Anti-D Ortho BioVue® System (ABD Confirmation Cassette)
Anti-A/Anti-B/Anti-A,B/Anti-D/Control/Anti-IgG,-C3d; polyspecific Ortho BioVue® System (Newborn Cassette)
Anti-A/Anti-B/Anti-D/Anti-D/Anti-K/Control Ortho BioVue® System (ADK Cassette)
Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette)
Anti-K Ortho BioVue® System (K Cassette)
Anti-K Control Ortho BioVue® System (K/Control Cassette)
Anti-A, Anti-B, Anti-A,B Anti-D, Anti-D, Control Ortho BioVue® System (ABO-DD Grouping Cassette)

CLASSIFICATION: Annex II List A

CONFORMITY ASSESSMENT ROUTE: Annex IV

BioVue Blood Grouping Reagents

DECLARATION OF CONFORMITY (continued)

Ortho-Clinical Diagnostics, Inc. hereby declares that the products stated above 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
- EN 13641: September 2000 Elimination or reduction of risk of infections related to in vitro diagnostic reagents
- EN 12740: July 1999 Biotechnology – Laboratories for research, development and analysis – Guidance for handling, inactivating and testing of waste
- prEN 375: August 2000 – Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- prEN 980: March 2001 Graphical symbols for use in the labelling of medical devices

NOTIFIED BODY:

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

EC DESIGN EXAMINATION CERTIFICATE:

V7 02 07 20533 007

EC CERTIFICATE:

V1 02 07 20533 005

PLACE, DATE OF ISSUE:

Raritan, NJ, U.S.A.
2002-10-28

SIGNATURE:

for Mizanu Kebede 11/12/02
Executive Site Director,
Quality Regulatory and Compliance