



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  
Johnson and Johnson  
50-100 Holmers Farm Way  
High Wycombe  
Buckinghamshire HP12 4DP  
United Kingdom

**PRODUCT:** Ortho AutoVue® Innova  
Ortho AutoVue® Ultra

**CLASSIFICATION:** Non-annex II

**CONFORMITY ASSESSMENT  
ROUTE:** Annex III

Ortho-Clinical Diagnostics, Inc. hereby declares Ortho AutoVue Innova and Ortho AutoVue Ultra 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
- ISO 14971: 2000 (E) Medical devices – Application of risk management to medical devices

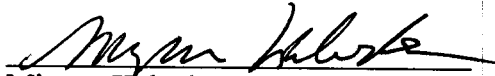
## DECLARATION OF CONFORMITY (continued)

- EN 591: March 2001 Instructions for Use for IVD Instruments for Professional Use.
- EN 1658: December 1996 Requirements for Marking of IVD instruments.
- EN 980: August 2002 Graphical symbols for use in the labeling of medical devices
- EN 61326: 1997/A1: 1998/ A2:2001 Electrical Equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.
- EN 61010-1: 2001 (2<sup>nd</sup> Edition) Safety of electrical measurement, control and laboratory equipment.
- EN /ISO 13485: 2000
- ISO 13485: 1996 Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001: 1994

**PLACE, DATE OF ISSUE:**

Raritan, NJ, U.S.A., 9/27/04  
Date

**SIGNATURE:**

  
Mizanu Kebede  
Executive Director,  
Quality, Regulatory, Compliance