



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:

Selectogen 2 x 3 mL
Surgiscreen 3 x 3 mL
Selectogen 2 x 10 mL
Surgiscreen 3 x 10 mL
Resolve Panel A 11 x 3 mL
Resolve Panel B 11 x 3 mL

**CLASSIFICATION:
CONFORMITY ASSESSMENT
ROUTE:**

Annex II List B

Annex IV

Ortho-Clinical Diagnostics, Inc. hereby declares BioVueScreen, Papain and BioVueScreen Ficin 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
- prEN 13612: September 2001 Performance evaluation of in vitro diagnostic medical devices

DECLARATION OF CONFORMITY (continued)

- prEN 13640: September 2001 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: 2002 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
- prEN 980: August 2002 Graphical symbols for use in the labelling of medical devices

NOTIFIED BODY:

TÜV Product Service GmbH
Nichtaktive Medizinprodukte
Ridlerstr. 65
80339 Munchen
Germany

EC CERTIFICATE:

V1 02 07 20533 005

PLACE, DATE OF ISSUE:

Raritan, NJ, U.S.A., 2013-05-29
Date

SIGNATURE:


Mizanu Kebede
Executive Director,
Quality, Regulatory, Compliance