



**DECLARATION OF CONFORMITY**

**Manufacturer:** Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester  
New York 14626  
USA

**Authorized Representative:** Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend CF35 5PZ  
United Kingdom

**Declaration of Conformity – Directive 98/79/EC**

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

<b>Product Name:</b>	<b>Product Code:</b>
VITROS 350 Chemistry System	6802153
<b>Classification:</b>	Non-Annex II / General / GIVD (other)
<b>Conformity Assessment Route:</b>	Annex III

**STANDARDS APPLIED:**

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-3:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 3: Instruments for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices --- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

# Ortho Clinical Diagnostics

## DECLARATION OF CONFORMITY *(continued)*

### STANDARDS APPLIED *(continued)*

- EN 61326-2-6 / IEC 61326-2-6 - Electrical Equipment for Measurement, Control and Laboratory Use EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- EMC: EN61000-3-2      EN61000-4-2      EN61000-4-3      Safety:      IEC 61010-1  
         EN61000-3-3      EN61000-4-4      EN61000-4-5                              IEC 61010-2-81  
         EN61000-4-6      EN61000-4-11                              IEC 61010-2-101

Date of original CE-marking:                              2005-01-31

### Declaration of Non-Conformity – Directive 2011/65/EU

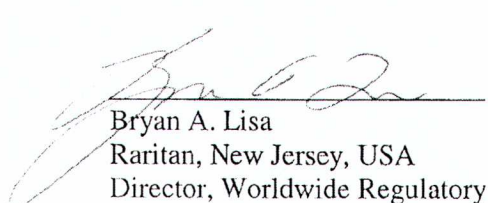
The object of the declaration described below is not in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

**Product Name:**

VITROS 350 Chemistry System

**Product Code:**

6802153

  
Bryan A. Lisa  
Raritan, New Jersey, USA  
Director, Worldwide Regulatory Affairs

2016 June 28  
**Date:** (year-month-day)