

## DECLARATION OF CONFORMITY

**Manufacturer:** Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester  
New York 14626-5101  
USA

**Authorized Representative:** Ortho-Clinical Diagnostics  
Johnson & Johnson  
50 - 100 Holmers Farm Way  
High Wycombe  
Buckinghamshire HP12 4DP  
United Kingdom

**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.**

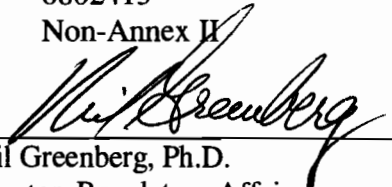
**Standards Applied:**

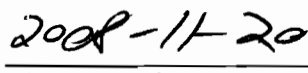
ISO 13485 Quality Systems – Medical devices- Supplementary requirements to ISO 9001  
ISO 14971 Medical Devices- Application of risk management to medical devices.  
EN 591 Instructions for use for in vitro diagnostic instruments for professional use  
EN 980 Graphical symbols for the use in the labeling of medical devices.  
EN 13612 Performance evaluation of in vitro diagnostic medical devices  
EN 61326-1 Electrical equipment for measurement, control and laboratory use-EMC requirements

<b>EMC:</b> EN55011	EN61000-4-4	EN61000-4-8	<b>Safety:</b> IEC 61010-1
EN61000-4-2	EN61000-4-5	EN61000-4-11	IEC 61010-2-101
EN61000-4-3	EN61000-4-6		

**Product Name:** VITROS 5600 Integrated System  
**Product Code:** 6802413  
**Classification:** Non-Annex II

Signature  
Printed Name  
Title

  
Neil Greenberg, Ph.D.  
Director, Regulatory Affairs  
Post Market Product Lifecycle

  
(year-month-day)

CE