Ortho Clinical Diagnostics
a Johnson & Johnson company

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

EMC:	EN55011	EN61000-4-4	EN61000-4-8	**Safety:**	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 _____ 2008-11-20
Printed Name Neil Greenberg, Ph.D. (year-month-day)
Title Director, Regulatory Affairs
Post Market Product Lifecycle

CE