



An Agilent Technologies Company

Tel: 800 / 382-2527  
Fax: 714 / 933-3222

7272 Chapman Avenue  
Garden Grove, CA 92841

www.hycorbiomedical.com

### Declaration of Conformity in accordance with ISO/IEC Guide 22

Name of Device	HY •TEC 288 System (including communication kits and printer)
Product Code	74000P, 74005P, 74007P, 728848, 135407
Device Description	The HY • TEC 288 System is an in vitro diagnostic instrument connected to a dedicated computer and printer and is designed for use in allergy and autoimmune enzyme-immunoassays and is in conformity with the provisions of the following EC Directives (mentioned below) when installed in accordance with the installation instructions contained in the product documentation:
Manufacturer	Hycor-An Agilent Technologies Company
Address	7272 Chapman Avenue, Garden Grove California, USA 92841
The devices described above are in conformity with Directive 2006/95/EC (Low Voltage Directive) of the European Council and of the Council and 2004/108/EC (Electromagnetic Compatibility Directive amended by Directives 91/263/EEC, 92/31/EEC and 93/68/EEC) of the Official Journal of European Union The devices are classified as "General IVDs" and as such this declaration of conformity is self certified.	
The following standards were referenced and taken into consideration:	
EN 61010-1: 2001	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use-Part 1: General Requirements
EN 61010-2-081: 2001 +A1:2003	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use-Part 2-81: Particular Requirements for automatic and semi-automatic Laboratory Equipment for Analysis and other Purposes
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-101: Particular requirements for <i>in vitro</i> diagnostic (IVD) medical devices
EN 61326-1:2006	Electrical Equipment for Measurement, Control and Laboratory Use-EMC Requirements
EN 55011: 2007	Emission - Class B (Industrial, Scientific and Medical (ISM) equipment
EN 61000-3-2:2006	Electromagnetic Compatible (EMC) Limits for Harmonic current emissions
EN 61000-3-3 +A1 +A2	Limitation of voltage fluctuations and flicker
EN 61000-4-2: 2001	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006	Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2004	Electrical Fast Transient/Burst Immunity
EN 61000-4-5:2006	Electromagnetic compatibility (EMC) -- Part 4-5: Testing and measurement techniques - Surge immunity test
EN 61000-4-6: 1996 +A1: 2001	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted RF disturbances
EN 61000-4-11:2004	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short

Name  
Randy Wilson  
Director, Global Regulatory Affairs  
Agilent Technologies Inc

Signature

11 Feb 09  
Date:

Date of Issue	
Place of Issue	Hycor-An Agilent Technologies Company

Hycor Europe  
Tel: +31 (0)170 312 5773  
Fax: +31 (0)170 312 5760

Hycor UK  
Tel: +44 (0)121 445 7111  
Fax: +44 (0)121 445 7117