



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

Name of Device	Hycor Allergy Assays
Device Description	Box: HYTEC Allergen Discs; Box: HYTEC 100 Tubes; PM Test Kit; Total IgE Kits; HYTEC Specific IgG Ref. Disc; VAST PD IgE Antibody Disc/25 vial; HYTEC Specific IgG 100 Test; HYTEC Specific IgE Ref. Disc 100T Classical; HYTEC Specific IgE Ref. Unit (7); HYTEC IgE Classical Control; HYTEC Specific IgG EIA Calibrator Set; Extended HYTEC Specific IgE Calibrator Set; Bulk Allergen Discs; HYTEC Specific Total IgE 300 Test;
Product Codes	19505; 19506; 19603; 72288; 73020; 74121; 71220; 74114; 74118; 74119; 74120; 74124; 74129; 7XXXXX; 74155;
Manufacturer	Hycor Biomedical Inc.
Address	7272 Chapman Avenue, Garden Grove California, USA 92841
Authorized Representative	Hycor Biomedical Ltd Pentlands Science Park, Bush Loan Penicuik, Midlothian, Scotland, EH26 OPL
<p>The devices described above are in conformity with Directive 1998/79/EC of European Parliament and of the Council of 27th October 1998 published in the Official Journal of European Union on 7th December 1998 on In-Vitro Diagnostic Medical Devices. The devices are classified as "General IVDs" and as such this declaration of conformity is self certified.</p>	
Additional Information	

Name
 Solmaz M. Shaida _____ *S.M. Shaida* _____ *July 19, 2010*
 Quality Manager, Hycor Biomedical Inc Signature Date.

Date of Issue	<i>19 July 2010</i>
Place of Issue	Hycor Biomedical Inc., Garden Grove, CA USA



**Declaration of Conformity
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Name of Device	Hycor Allergy Components and Accessories
Device Description	Stripcaps 9.35MM; HYTEC™ Tubes 9mm x 45mm, 500; ENZ EIA Wash Solution 125ml; HYTEC Substrate Diluent; HYTEC pNPP Tablets 25 Tabs; HYTEC IgG Sample Diluent/80 ml; HYTEC Spec.Anti-IgG CJ/8ml; ENZ EIA Wash Solution; HYTEC Stop Solution 1000ml; Vial: Spec/Total IgE Conj; IgE Diluent; HYTEC Tubes 9mm x 45mm, Al; HYTEC Spec. IgE Conjugate 19.5ml (Classical); Specific IgE Negative Control; HYTEC Vial: IgE Conjugate/Classical 29ml; HYTEC 288 Precision Kit; 288 Cleaning Solution 480 ml
Product Codes	121004; 122004; 331026; 308050; 308053; 308076; 308077; 308126; 308151; 308174; 309046; 312500; 318094; 324005; 328276, 77020; 288197
Manufacturer	Hycor Biomedical Inc.
Address	7272 Chapman Avenue, Garden Grove California, USA 92841
Authorized Representative	Hycor Biomedical Ltd Pentlands Science Park, Bush Loan Penicuik, Edinburgh, EH26 OPL
<p>The devices described above are in conformity with Directive 1998/79/EC of European Parliament and of the Council of 27th October 1998 published in the Official Journal of European Union on 7th December 1998 on In-Vitro Diagnostic Medical Devices. The devices are classified as "General IVDs" and as such this declaration of conformity is self certified.</p>	
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 Solmaz M. Shaida _____ *S.M. Shaida* _____ *July 19, 2010*
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Name of Device	HYTEC 288 System (including communication kits and printer)
Product Code	74000P, 74005P, 74007P, 728848, 135407
Device Description	The HYTEC 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 Biomedical Inc.
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, Directive **1998/79/EC** (In-Vitro Diagnostic Medical Devices) and Directive **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
Solmaz Moghaddam
Quality Manager, Hycor Biomedical Inc


Signature

5/4/10
Date:

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