


Appendix I : Declaration of Conformity.

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

Name of Device:	Adenovirus-IgG,-IgA,-IgM; Aspergillus fumigatus-IgG,-IgA,-IgM; Bordetella pertussis-IgG,-IgA,-IgM; Lyme antibody (Borrelia burgdorferi)-IgG,-IgM; Brucella abortus-IgG,-IgA,-IgM; Candida albicans-IgG,-IgA,-IgM; Diphtheria-IgG; Epstein Barr Virus EA-IgG,-IgA,-IgM; Epstein Barr Virus EBNA-IgG,-IgA,-IgM; Epstein Barr Virus VCA-IgG,-IgA,-IgM; Echinococcus-IgG; FSME / TBEV-IgG,-IgM; Helicobacter pylori-IgG,-IgA,-IgM; Herpes 1-IgG,-IgA,-IgM; Herpes 2-IgG,-IgA,-IgM; Herpes1/2-IgG,-IgA,-IgM; HYSORB (RF-Absorbance); Influenza A-IgG,-IgA,-IgM; Influenza B-IgG,-IgA,-IgM; Measles-IgG,-IgA,-IgM; Mumps-IgG,-IgA,-IgM; Mycobacterium tuberculosis-IgG,-IgA,-IgM; Mycoplasma pneumoniae-IgG,-IgA,-IgM; Parainfluenza1/2/3-IgG,-IgA,-IgM; Poliomyelitis IgG; RSV (Resp-Syncytial-Virus) -IgG,-IgA,-IgM; Tetanus IgG; Varicella zoster-IgG,-IgA,-IgM; Yersinia enterocolitica-IgG,-IgA,-IgM.
Product Code:	ADV-1,-2,-3; ASP-1,-2,-3; BPT-1,-2,-3; BBG-1,-3; BRU-1,-2,-3; CAN-1,-2,-3; DIP-1; EBV EA-1,-2,-3; EBV EBNA-1,-2,-3; EBV VCA-1,-2,-3; ECC-1; FSM-1,-3; HEL-1,-2,-3; HSV1-1,-2,-3; HSV2-1,-2,-3; HSV1/2-1,-2,-3; HYS-1; IFA-1,-2,-3; IFB-1,-2,-3; MAS-1,-2,-3; MUM-1,-2,-3; MBT-1,-2,-3; MPP-1,-2,-3; PIF1/2/3-1,-2,-3; POL-1; RSV-1,-2,-3; TET-1; VAR-1,-2,-3; YER-1,-2,-3.
Manufacturer:	Hycor Biomedical Ltd
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<p>The device described above is in conformity with Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on In Vitro Diagnostic Medical Devices, published in the Official Journal on 7th December 1998. The devices are classed as 'General IVDs' and as such this declaration of conformity is self-certified.</p>	
Additional information:	



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Signed:	
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