

UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

EC Certificate - Full Quality Assurance System Approval Certificate

(Annex IV, section 3 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

Manufacturer

Princeton BioMeditech Corporation
4242 US Highway 1
Monmouth Junction
NJ 08852-1905
USA

Authorised Representative

Medical Technology Promedt Consulting
GmbH
Altenhofstrasse 80,
66386 St. Ingbert,
Germany

Scope of Certificate: The design, development, manufacture and distribution of in vitro diagnostic kits using rapid lateral flow immunoassay technology for detection and diagnosis of rubella antibody (professional use), pregnancy (self test), ovulation (self test), and male fertility (self test)

Device Classifications: Annex II List B and Self Test

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Certificate issued by:



Certification Manager
For UL International (UK) Ltd

UL International (UK) Ltd
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Old Portsmouth Road
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Certificate no: 303
Original certificate: 10 November 2003
Current certificate: 29 October 2009
Certificate expiry: 10 November 2012

