



EC CERTIFICATE

Health-Chem Diagnostics LLC

3341 SW 15th Street Pompano Beach
FL 33069 USA

EC Design – Examination Certificate

Annex III, section 6 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Device Descriptions:

In vitro diagnostic self-test device for semi-quantitative determination of Total and HDL cholesterol in blood

Model:

Total Cholesterol Test 15-021 A

Cholesterol Complete 15-019 A

File Number	A18093	Cycle Start Date	16 November 2011
Certificate No.	489.111116	Effective Date	16 November 2011
		Expiry Date	15 November 2016

Authorised by

Ivor Barrett
Certification Manager

For and on Behalf of UL International (UK) Ltd

We hereby declare that a design examination has been carried out on the device(s) listed per report 11NK13855, following the requirements of the national legislation to which the undersigned is subject, transposing Annex III section 6 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the design of the device(s) listed conforms with the relevant provisions of Annex III section 6 of the aforementioned directive as transposed into national legislation.

Notified Body

0843

00-NB-F0065 2.0

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom