HALYARD

EC Declaration of Conformity

Name of Products:	Diagnostic Products
Product Codes:	60480 - CLOtest 60407 - UREASE Control Tablets 60408 - CLOtest* DUO
GMDN Code:	52787 (*Helicobacter pylori* Urease IVD, Kit, Chromogenic)
Legal Manufacturer (Place of Issue):	Halyard Health, Inc. 5405 Windward Parkway Alpharetta, Georgia (GA) 30004, USA
EU Authorized Representative:	Halyard Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium
Product Standards:	EN ISO 13485:2003 EN ISO 14971:2009
Start of CE:	23-March-2015
Conformity Assessment Route:	Annex III
Device Classification, Rules:	Class I, Annex IX of 98/79/EEC

I, the undersigned, hereby declare that the above specified medical devices meet the applicable provisions of European In Vitro Diagnostic Medical Devices Directive 98/79/EEC and are in accordance with Annex III of the EEC Directive, supported by the Conformity Assessment Procedure, and adhering to the essential requirements in accordance with Annex I of the Directive 98/79/EEC.

This declaration is based on the existing Technical Documentation as per Annex III. CE marking carried out as per Annex X of the Directive 98/79/EEC.

All supporting documentation that contains proof of compliance to the aforementioned Directives is retained under the premises of Halyard Health, Inc. This declaration applies to all devices from the signature date forward.

Authorized Signature:

Name: Thomas Kozma, PhD
Title: Director, Regulatory Affairs
Halyard Health, Inc.
Date: 28-Jul-2015