



Abbott Molecular Inc.
 1300 East Touhy Avenue
 Des Plaines, IL 60018
 USA

Declaration of Conformity for Self Declared IVDs

IVDD Category: Self Declared

Legal Manufacturer's Name: Abbott Molecular Inc.
 Legal Manufacturer's Address: 1300 E. Touhy Ave.
 Des Plaines IL USA 60018

Name of Authorized Representative in Europe: Abbott GmbH & Co. KG
 Address of Authorized Representative in Europe: Max-Planck-Ring 2 D-65205
 Wiesbaden- Germany

List Number(s) of Device	Name(s) and Description(s) of Device
6L87-02	Abbott Uracil-N-Glycosylase(UNG)
1L31-67	Abbott RealTime CT Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
2G28-67	Abbott RealTime CT/NG Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
4J86-67	Abbott RealTime HCV Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
2G31-67	Abbott RealTime HIV-1 Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
8L07-67	Abbott RealTime CT/NG Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
1N30-67	Abbott RealTime HCV Including Uracil-N-Glycosylase (UNG) Procedure
6L18-67	Abbott RealTime HIV-1 Amplification Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
3N23-67	Abbott RealTime HIV-1/HCV maxCycle with Amplification Reagent Extended Use Including Uracil-N-Glycosylase (UNG) Procedure
02G31-66	Abbott RealTime HIV-1 Amplification Including Uracil-N-Glycosylase (UNG)
04J86-66	Abbott RealTime HCV Amplification Including Uracil-N-Glycosylase (UNG)
04N66-66	Abbott RealTime HIV-1 Qualitative Including Uracil-N-Glycosylase (UNG)
02N09-66	Abbott RealTime High Risk HPV Amplification Including Uracil-N-Glycosylase (UNG)
02G28-66	Abbott RealTime CT/NG and CT Amplification Including Uracil-N-Glycosylase (UNG)
08K24-66	Abbott RealTime HCV Genotype II Amplification Including Uracil-N-Glycosylase (UNG)





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08L21-66	Uracil-N-Glycosylase (UNG) for use in conjunction with Abbott RealTime HCV Genotype II Assay
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Name of technical documentation owner
 Address of technical documentation owner

Abbott Molecular Inc.
 1300 E. Touhy Ave.
 Des Plaines II USA 60018

I, the undersigned, hereby declare that the *in vitro* diagnostic medical device(s) described above and bearing the CE-Marking, conform with the applicable provisions of *Medizinproduktegesetz (Medical Devices Act, Germany)* transposing EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices.

This declaration is made in accordance with Annex III of the IVD Directive 98/79/EC.

Signature:

 _____

Full Name (printed):

Pam Swatkowski _____

Position:

Director, Regulatory Affairs _____

Date:

May 26, 2015 _____

Date Issued:

May 26, 2015 _____

Place:

Abbott Molecular Inc. Des Plaines II USA 60018

