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Epitope Diagnostics,Inc.

Document #: DOC KT602 V3

DECLARATION OF CONFORMITY

Manufacturer:

Epitope Diagnostics, Inc
7110 Carroll Road
San Diego, CA, 92121
USA

IVD Medical Devices:

Product Name	*Product Number*
EDI™ Total GLP-1 ELISA Kit	KT-602

WE, Epitope Diagnostics, Inc. declare and ensure with sole responsibility that products listed above meet the applicable requirements of the European *In Vitro* Diagnostic Directive 98/79/EC.

Device Classification: Article 9, section 1, "Other" IVD

Conformity Assessment Route: This declaration is based on conformity assessment procedure of Directive 98/79/EC Annex III, excluding III.6

EDMA Code: 12060102

EC Authorized Representative:
Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

ISO 13485:2016 Certificate No. 017257

Signature of Company Representative:

Name: Stefanie Lenart-Dallezotte
Title: Quality Assurance/Regulatory Affairs Manager Date: April 10, 2013