Epitope Diagnostics, Inc.
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Document No.: DoC KT-313 V9

DECLARATION OF CONFORMITY

(According to Directive 98/79/EC, on in-vitro diagnostic medical devices)

Manufacturer: Epitope Diagnostics, Inc.
7110 Carroll Road
San Diego, CA 92121
United States of America

IVD Medical Device:

Product Name	EpiTuub® iFOB Rapid Test Kit
Product Number	KT-313

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: 12.70.03.21 (Fecal Occult Blood – RT & POC)

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

ISO 13485:2016 Certificate No. 020741, Registration No. 3387-01

This Declaration of Conformity is based on European Parliament and the Council's directive 98/79/EC Annex III, and signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive 98/79/EC Annex III.

Signature of a Company's Representative:

ujjavala

Name: Ujjavala Umrigar
Title: Regulatory Affairs Associate Date: April 28, 2021