



Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological
Development Area
Hangzhou, 310018, P.R.China
T: +86 571 81638000
F: +86 571 81638001

Declaration of Conformity

DoC #: TT-008- 001M

Legal Manufacturer: Abon Biopharm (Hangzhou) Co., Ltd.
Legal Manufacturer's Address: #198 12th Street East, Hangzhou
Economic & Technological Development Area,
Hangzhou, 310018, P. R. China
EC Representative's Name: MT Promedt Consulting GmbH
EC Representative's Address: Ernst-Heckel-Straße 7
66386 St. Ingbert/Germany

**declares, that the product
Product Name, Model(s) and EDMA code:**

Product Name	Brand	Model	EDMA code	EDMA Description
FOB One Step Fecal Occult Blood Test Device (Feces)	ABON	TFO-602	12 03 90 04 00	Fecal Occult Blood(IC)
FOB One Step Fecal Occult Blood Test Device (Feces)	Clearview	TFO-602	12 03 90 04 00	Fecal Occult Blood(IC)

**as described above are in conformity with the requirements as defined in TT-0008 Appendix C: List
of Applicable Standards.**

Additional information:

Management System: QSA-000, Quality System Manual
Applied Standard ISO13485:2016
EN ISO13485:2016
**Certification Body of
ISO13485 certificate:** TÜV SÜD Product Service GmbH
Zertifizierstelle, Ridlerstrasse 65 • 80339 München, Germany
Conformity Pathway: IVD Directive 98/79/EC Article 9 and Annex III (excluding
III.6)
Classification: Other IVD



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We (manufacturer) declare on our own responsibility that the in vitro diagnostic medical device complies with all applicable provision of the Directive 98/79/EC and meets the Essential Requirements according to Annex I of this Directive.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Date Signed:

2023.07.26

Yuki Fang

Yuki Fang
RA Manager
Signed for on behalf of
Abon Biopharm (Hangzhou) Co., Ltd.



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Version/Date	Summary of Changes
TT-008-001A 2009.9.04	New
TT-008-001L 2023.05.15	<ol style="list-style-type: none">1. Update EC representative's address2. Add Clearview brand3. Add the Description of EDMA code4. Update Conformity Pathway5. Update the declare description6. Add DOC change summary
TT-008-001M 2023.07.26	Update the declare description