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-022-006S

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: Altenhofstrasse 80
66386 St. Ingbert/Germany

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

MDMA One Step Ecstasy Test Strip (Urine)	DMD-101	12 09 01 02 00
MDMA One Step Ecstasy Test Device (Urine)	DMD-102	12 09 01 02 00
MET One Step Methamphetamine Test Strip (Urine)	DME-101	12 09 01 02 00
MET One Step Methamphetamine Test Device (Urine)	DME-102	12 09 01 02 00
MET 500 One Step Methamphetamine Test Strip (Urine)	DME-U101	12 09 01 02 00
MET 500 One Step Methamphetamine Test Device (Urine)	DME-U102	12 09 01 02 00
MET 300 One Step Methamphetamine Test Strip (Urine)	DME-A101	12 09 01 02 00
MET 300 One Step Methamphetamine Test Device (Urine)	DME-A102	12 09 01 02 00

as described above are in conformity with the requirements as defined in TT-0022 Appendix C: List of Applicable Standards.

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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

I, the undersigned, hereby declare that the medical devices specified above conform to the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: 2021.12.27

Yuki Fang

Yuki Fang
RA Manager
Abon Biopharm (Hangzhou) Co., Ltd.