



Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological
Development Area
Hangzhou, 310018, P.R.China
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Declaration of Conformity

DoC #: TT-043-001B

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:

Alere™ hCG Easy (25 mIU/mL)

UPK009C 12 70 05 02 00

as described above are in conformity with the requirements as defined in TT-0043
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, Section 1, Annex IV
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:

2021.12.28

Yuki Fang

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