



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-006-001G

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:**

Strep A Rapid Test Strip (Throat Swab)	IST-501	15 70 01 03 00
Strep A Rapid Test Device (Throat Swab)	IST-502	15 70 01 03 00
Clearview [®] Strep A Dipstick 2	IST-501	15 70 01 03 00
Clearview [®] Strep A Cassette 2	IST-502	15 70 01 03 00

as described above are in conformity with the requirements as defined in TT-0006 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

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

RA Manager

Abon Biopharm (Hangzhou) Co., Ltd.



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Declaration of Conformity Amendment for TT-006 IST-501& IST-502 Product

The Declaration of Conformity amendment is to serve as an official extension of the Declaration of Conformity and to notify of the EC Representative's address and product name change for IST-501& IST-502.

The EC Representative's address has changed from Altenhofstrasse 80, 66386 St. Ingbert/Germany to Ernst-Heckel-Straße 7 66386 St. Ingbert/Germany.

The product name of IST-501 has changed from Clearview® Strep A Dipstick 2 to Clearview™ Strep A Dipstick 2. The product name of IST-502 has changed from Clearview® Strep A Cassette 2 to Clearview™ Strep A Cassette 2.

Per MDCG2022-6 Guidance on significant changes regarding the transitional provision under Article110(3) of the IVDR(May 2022), the implementation of change to the EC Representative's address and product name are not significant as these changes have no impact to design or intended purpose of the products.

Product Name	Model
Strep A Rapid Test Strip (Throat Swab)	IST-501
Strep A Rapid Test Device (Throat Swab)	IST-502
Clearview™ Strep A Dipstick 2	IST-501
Clearview™ Strep A Cassette 2	IST-502

The latest Declaration of Conformity date: 27 Dec 2021

Date Signed:

2021.09.02

Yuki Fang

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