

中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



193301A0/007305

号码 No.

兹证明：在所附一致声明上的艾博生物医药(杭州)有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of ABON BIOPHARM (HANGZHOU) CO., LTD on the annexed DECLARATION OF CONFORMITY is genuine.



China Council for the Promotion
of International Trade

授权签字:

Authorized
Signature:

Lu Juanjuan

日期: 2019年04月15日
(Date: Apr. 15, 2019)



艾博生物医药（杭州）有限公司
Abon Biopharm (Hangzhou) Co., Ltd.

Declaration of Conformity

DoC #: TT-038-001G

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
Notified Body: Institut pro testovani a certifikaci a.s.
Notified Body No.: CE1023

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

ABON HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) IHC-302 15 70 02 02 00

as described above are in conformity with the requirements as defined in TT-0038 Appendix C: List of Applicable Standards.

Additional information:

Management System: QSA-000, Quality System Manual
Applied Standard of Management System: ISO13485:2016, EN ISO13485:2016
Certification Body: Institut pro testovani a certifikaci a.s.
EC Certificate No.: No. 11 0497 QS/NB/d, No. 11 0498 CN/NB/d
Conformity Pathway: Directive 98/79/EC Article 9, Section 2, Annex IV
Classification: List A 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:

April 18, 2018

Ivy Wei
 RA Manager
 Abon Biopharm (Hangzhou) Co., Ltd.

杭州经济技术开发区12号大街（东）198号
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认字第 19028897 号

兹证明前面文书上中国国际贸易
促进委员会商事证明专用章(37)的印
章和授权签字人陆娟娟的签字属实。



中华人民共和国外交部 (330)
一九九九年四月十六日 杭州

陆娟娟



Yukarıdaki imza ve mühürün Zhejiang Eyaleti Halk
Hükümeti Dış İlişkiler Bürosu'na ait olduğu tasdik
olunur.

Genel No : 25016061

Özel No : 2354

Tarih : 17.04.2019

T.C. ŞANHAY BAŞKONSOLOSLUĞU

S. Doğa ÖZMEZ

S. Doğa ÖZMEZ
Vice Consul

