



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 11 0497 QS/NB

The quality system of manufacturer

ABON Biopharm (Hangzhou) Co., Ltd.

**#198, 12th Street East, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, P. R. China**

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

Hepatitis Rapid Test Device

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2016-06-14
Valid until: 2021-06-14
First Issued: 2011-06-16
Revision: d

Date: 2016-06-14



R. Pavelčík
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 11 0497 QS/NB
issued for manufacturer:

ABON Biopharm (Hangzhou) Co., Ltd.
**#198, 12th Street East, Hangzhou Economic & Technological
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Product:

Name: HBsAg Hepatitis B Surface Antigen Rapid
Test Device
(Whole Blood/Serum/Plasma)

Trade name(s): ABON™
Model(s): IHBsg-402
Classification: List A
GMDN: 41987

Name: HCV Hepatitis C Virus Rapid Test Device
(Serum/Plasma)


Trade name(s): ABON™
Model(s): IHC-302
Classification: List A
GMDN: 45719

Facility(ies):

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

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Certificate History:

| Revision | Date | Reference Number | Action |
|----------|------------|------------------|--------------------------------|
| | 2011-06-16 | 813600150 | Certification |
| a | 2012-05-18 | 343601534 | Significant change of design |
| b | 2014-12-29 | 813600397 | Significant change of design |
| c | 2015-06-30 | 813600460 | Insignificant changes approval |
| d | 2016-06-14 | 813600540 | Re-certification process |

Date: 2016-06-14



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023