



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



*Paulík*  
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

Date: 2016-06-14



  
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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