



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 14 11 58228 006

Manufacturer: **ABON Biopharm (Hangzhou) Co., Ltd.**

#198, 12th Street East
Hangzhou Economic & Technological
Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **MT Promedt Consulting GmbH**

Altenhofstrasse 80
66386 St. Ingbert
GERMANY

Product Category(ies): **Products for determination of infection markers and products for self testing as specified in the attachment**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH14170EXT01

Valid from: 2015-01-17
Valid until: 2020-01-16



Hans-Heiner Junker

Date, 2014-12-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 3



Product Service

EC Certificate**Full Quality Assurance System**

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 14 11 58228 006

Model(s):

Early Detection One Step Pregnancy Test,
Early Detection One Step Ultra Pregnancy Test,
+/- Early Detection One Step Pregnancy Test,
+/- Early Detection One Step Ultra Pregnancy Test,
Easy Prediction One Step Ovulation Test,
Easy Prediction One Step Ultra Ovulation Test,
Easy Detection One Step Menopause Test,
PSA Prostate Specific Antigen
Semi-Quantitative Rapid Test,
PSA Prostate Specific Antigen
Semi-Quantitative Ultra Rapid Test,
Chlamydia Rapid Test,
CMV IgM Antibody Rapid test,
Rubella IgM Antibody Rapid Test,
Toxo IgM Antibody Rapid Test,
ToRCH Toxo/Rubella/CMV/HSV 1/2 IgM
Antibodies Combo Rapid Test

Facility(ies):

ABON Biopharm (Hangzhou) Co., Ltd.
#198, 12th Street East, Hangzhou Economic & Technological,
Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC
OF CHINA

Attachment for Certificate No V1.14.11.58228.006

Supplement 001 dated 2015-01-17



Product Service

For the product(s)/product category (ies):

Pregnancy (HCG) Test for self testing

Ovulation (LH) Test for self testing

Menopause (FSH) Test for self testing

PSA Rapid Test

Chlamydia Rapid Test

CMV Rapid Test

Rubella Rapid Test

Toxo Rapid Test

ToRCH Combo Rapid Test

Munich, CRT2, 2014-12-17

Hans-Heiner Junker
Certification Medical Technology

Page 3 of 3