



# ISO13485 certificate



DAKKS  
Deutscher  
Akreditierungsausschuss  
D-2041321-01-00

TUV SÜD  
Product Service

**Certificate**  
No. Q5 061317 0005 Rev. 00

**Holder of Certificate:** Xiamen Boson Biotech Co., Ltd.  
90-94 Tianfeng Road  
Jimei North Industrial Park  
361021 Xiamen, Fujian  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Xiamen Boson Biotech Co., Ltd.  
90-94 Tianfeng Road, Jimei North Industrial Park, 361021  
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

**Scope of Certificate:** Design and Development, Production and Distribution of  
In Vitro Diagnostic kits for detection of Infection Diseases,  
Tumour Markers, Drug Abuse, Hormones, Cardiac Markers  
and Related Biomaterial

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned  
above has established and is maintaining a quality management system, which meets the  
requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1807513  
**Valid from:** 2018-10-31  
**Valid until:** 2021-10-30

**Date:** 2018-09-27   
Stefan Preiß

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