



Certificate

No. Q5 094093 0003 Rev. 00

Holder of Certificate: **Biohit Healthcare (Hefei) Co., Ltd**

Building D9 floor1-4, Innovation Park
West Wangjiang Road No.800
High-Tech Zones
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Biohit Healthcare (Hefei) Co., Ltd
Building D9 floor1-4, Innovation Park, West Wangjiang Road
No.800, High-Tech Zones, 230088 Hefei, Anhui, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Design, Development, Production and
Distribution of Assay Kits for PEPSINOGEN I ,
PEPSINOGEN II, GASTRIN-17 Assay with ELISA,
Fluorescence Immunochromatographic and
Chemiluminescent Method,
and Fluorescence Immunoassay Analyzer**

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.:

SH18103204_RA

Valid from:

2019-04-06

Valid until:

2022-04-05

Date,

2019-02-11

Stefan Preiß