





Product Service

Certificate

No. Q6 085903 0009 Rev. 00

Holder of Certificate: SHANDONG ZHENFU MEDICAL DEVICE

CO., LTD.

High-tech Industrial Park

276800 Rizhao City, Shandong Province PEOPLE'S REPUBLIC OF CHINA

SHANDONG ZHENFU MEDICAL DEVICE CO., LTD. Facility(ies):

High-tech Industrial Park, 276800 Rizhao City, Shandong

Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Production and Sales of bacterial/viral filter, Scope of Certificate:

> pulmonary function test filter, heat and moisture exchange filter, precision liquid filter, TPE infusion set with needle, TPE infusion set without needle.

EN ISO 13485:2016 **Applied Standard(s):**

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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

BJ1991104 Report No.:

Valid from: 2020-01-03 Valid until: 2022-11-19

2020-01-03 Date,

Christoph Dicks

Head of Certification/Notified Body





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