

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
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Product Service

# EC Certificate

Production Quality Assurance System  
 Directive 93/42/EEC on Medical Devices (MDD), Annex V  
 (Devices in class I in sterile conditions, sterilised systems or procedure packs)  
**No. G2S 085903 0006 Rev. 01**

**Manufacturer** **SHANDONG ZHENFU MEDICAL DEVICE CO., LTD.**  
 High-tech Industrial Park  
 276800 Rizhao City, Shandong Province  
 PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
 Eiffestraße 80, 20537 Hamburg, GERMANY

**Product Category(ies):** **Bacterial/viral filter,heat and moisture exchange filter, pulmonary function test filter, precision liquid filter, TPE infusion set without needle.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

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Stefan Preiß

