



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 17 07 99160 002**Manufacturer:****BLUEMED HEALTHCARE CO., LTD.**

Rm 2737, 1010 Huaihai Middle Road

200021 Shanghai

PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:****Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

Product Category(ies):**Sterile Cutting Gauze,
Sterile Adhesive Surgical Dressing,
Wound Plaster, Sterile Surgical Gown,
Non-woven Swabs without X-ray Thread**

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.

Report No.:

SH17108201

Valid from:

2017-11-17

Valid until:

2022-11-16

**Date,** 2017-11-17

Stefan Preiß

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

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Shanghai, PEOPLE'S REPUBLIC OF CHINA**