



Certificate

No. Q6 102991 0001 Rev. 00

Holder of Certificate: Taizhou Runmei

Sanitary Products Co., Ltd.

South Factory of F2, Building 4

No.80 Xiaqi Road

Suchen Town, Hailing District 225319 Taizhou, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Taizhou Runmei Sanitary Products Co., Ltd.

South Factory of F2, Building 4, No.80 Xiaqi Road, Suchen Town, Hailing District, 225319 Taizhou, Jiangsu Province, PEOPLE'S

REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Production and Distribution of Sterile Pad

(Alcohol Pad)

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

Report No.:

SH19147401

Valid from:

2019-10-08

Valid until:

2022-10-07

Date,

2019-10-08

Stefan Preiß

1. Pumil

Head of Certification/Notified Body





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 102991 0002 Rev. 00

Manufacturer

Taizhou Runmei

Sanitary Products Co., Ltd.

South Factory of F2, Building 4 No.80 Xiaqi Road Suchen Town, Hailing District 225319 Taizhou, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile Pad (Alcohol Pad)

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.:

SH19147401

Valid from:

2019-10-08

Valid until:

2024-05-26

Date,

2019-10-08

Stefan Preiß

1. Pumil

Head of Certification/Notified Body

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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 102991 0002 Rev. 00

Facility(ies):

Taizhou Runmei Sanitary Products Co., Ltd. South Factory of F2, Building 4, No.80 Xiaqi Road, Suchen Town, Hailing District, 225319 Taizhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA