DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

认证证书

证书号. Q5 103156 0002 Rev. 00

证书持有者： **上海亚澳医用保健品有限公司**

中华人民共和国上海市浦东新区六陈路999号 201202

生产场地： 上海亚澳医用保健品有限公司

中华人民共和国上海市浦东新区六陈路999号 201202

认证标志：



认证范围： **设计和开发、生产和分销：**

透明敷料、敷料贴、泡绵敷料、眼贴、外科手术包

认证标准： EN ISO 13485:2016

医疗器械 - 质量管理体系 - 用于法规的要求

(ISO 13485:2016)

DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

报告号： SH20145502

生效期： 2020-07-01

有效期： 2023-06-30

发证日期, 2020-07-01

Christoph Dicks

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

本证书是由具有法律效力的英文证书翻译而来

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 103156 0002 Rev. 00

Holder of Certificate:

Shanghai ISO Medical Products Co., Ltd
999 Liu Chen Rd
Pudong New Area
201202 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shanghai ISO Medical Products Co., Ltd
999 Liu Chen Rd, Pudong New Area, 201202 Shanghai,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Design and Development,
Production and Distribution of
Transparent Film Dressing, Island Dressing,
Foaming Dressing, Eyelid Occlusion Dressings,
Surgical Dressing Kit.**

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.: SH20145502

Valid from: 2020-07-01
Valid until: 2023-06-30

Date, 2020-07-01

Christoph Dicks
Head of Certification/Notified Body

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