CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

Certificate

No. Q5 056820 0035 Rev. 08

Holder of Certificate: **GRI Medical & Electronic Technology Co., Ltd.**
1805 Honggao Road
314031 Jiaxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Non-active Medical Devices(See following Pages)**

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 056820 0035 Rev. 08

Report No.: SH26030201

Valid from: 2026-09-01
Valid until: 2029-08-31

Date, 2026-08-04

Christoph Dicks
Head of Certification/Notified Body

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

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

GRI Medical & Electronic Technology Co., Ltd.
1805 Honggao Road, 314031 Jiaxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Non-sterile or Sterile Disposable Medical Drapes and Covers for medical use, Non-sterile or Sterile Plastic Orthopedic Devices for medical use, Non-sterile or Sterile Health Care Devices for medical use, Non-sterile or Sterile Surgical Operation Assist Devices for medical use, Non-sterile or Sterile Surgical Drapes and Gowns for medical use, Sterile Incision Device for medical use, Non-sterile or Sterile Securement Device for medical use, Sterile Procedure Pack for medical use, Non-sterile or Sterile Insufflation Tubing for medical use, Non-sterile or Sterile Basins and Trays for medical use, Non-sterile or Sterile Esmark Bandage for medical use, Non-sterile or Sterile Suction Tubing for medical use, Non-sterile or Sterile Medical Forceps and Clamps for medical use, Non-sterile or Sterile OR Towel for medical use, Non-sterile or Sterile Sharp Management Devices for medical use, Non-sterile or Sterile Veress Needle for medical use, Non-sterile or Sterile Equipment Covers for medical use, Non-sterile or Sterile Skin Marker for medical use, Non-sterile or Sterile Suction Tip for medical use, Non-sterile or Sterile Sponge Stick for medical use, Non-sterile or Sterile Waste Collection Device for medical use, Non-sterile or Sterile Tip Cleaner for medical use, Patient Warming for medical use, Patient Securement for medical use, Room Turnover Kits for medical use, Non-sterile or Sterile Bulb Syringe for medical use, Non-sterile or Sterile Ophthalmic Absorbents for medical use, Sterile Single-use endoscopic haemostatic agent applicator cannula for medical use, Isolation Gown for medical use
Design and Development Ophthalmic Caliper for medical use, Eye shield for medical use and Underpads for medical use.

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No. Q5 056820 0035 Rev. 08

GRI Medical & Electronic Technology Co., Ltd.
No. 533 Kanghe Road, Gaozhao Street, Xiuzhou Zone, 314031
Jiaxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Production of Non-sterile or Sterile Surgical Gowns for medical use, Non-sterile or Sterile Surgical Drapes for medical use, Non-sterile or Sterile Sharp Management Device for medical use, Non-sterile or Sterile Basins and Trays for medical use, Non-sterile or Sterile Esmark Bandage for medical use, Non-sterile or Sterile Suction Tubing for medical use, Non-sterile or Sterile Medical Forceps and Clamps for medical use, Non-sterile or Sterile Suction Tip for medical use, Non-sterile or Sterile Surgical Operation Assist Devices for medical use, Non-sterile or Sterile Tip Cleaner for medical use, Underpads for medical use, Patient Warming for medical use, Patient Securement for medical use, Room Turnover Kits for medical use, Ophthalmic Caliper for medical use, Isolation Gown for medical use, Non-sterile or Sterile Sponge Stick for medical use, Non-sterile or Sterile Bulb Syringe for medical use, Non-sterile or Sterile Equipment Covers for medical use, Non-sterile or Sterile Ophthalmic Absorbents for medical use, Non-sterile or Sterile OR Towel for medical use, Non-sterile or Sterile Securement Device for medical use, Non-sterile or Sterile Skin Markers for medical use, Non-sterile or Sterile Waste collection device for medical use, Non-sterile or Sterile Veress Needle for medical use, Sterile Incision Device for medical use, Non-sterile or Sterile Insufflation Tubing for medical use, Sterile Procedure Pack for medical use, Eye shield for medical use.

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Certificate

No. Q5 056820 0035 Rev. 08

GRI Medical & Electronic Technology Co., Ltd.
No. 22, Fuqiang Road, Jiujiang Economic Development Zone,
241000 Wuhu, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

Production of Underpads for medical use.

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

Certificate

No. Q5 056820 0035 Rev. 08

GRI Medical & Electronic Technology Co., Ltd.
Industrial Zone, Yijiang Town, Nanling, 241311 Wuhu, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

Production of Non-sterile or Sterile Surgical Drapes and Gowns for medical use, Non-sterile or Sterile Surgical Operation Assist Devices for medical use, Isolation Gown for medical use, Patient Securement for medical use, Non-sterile or Sterile Ophthalmic Absorbents for medical use.

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