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

MDSAP
Medical Device Single Audit Program

C E R T I F I C A T E

No. QS6 019931 0024 Rev. 00

Certificate Holder:

GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstr. 26
86916 Kaufering
GERMANY

Certification Mark:

Scope of Certificate:

Design and Development, Production, Distribution, Installation and Servicing of Defibrillators, Patient Monitoring and Resuscitation Equipment including Accessories, External Battery Chargers and Power Supplies, Medical Software including Telemetry as well as Installation and Service Provision of Telemedical Software/Systems in the Cloud

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Health Canada, Japan MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 019931 0024 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F009260**
Report No.: **713411696**
Effective Date: **2026-09-15**
Expiry Date: **2029-09-14**

Date of Issue: 2026-09-23

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS

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

MDSAP
Medical Device Single Audit Program

TÜV SÜD

C E R T I F I C A T E

No. QS6 019931 0024 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

Facility(ies):

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstr. 26, 86916 Kaufering, GERMANY

GS Elektromedizinische Geräte G. Stemple GmbH
Günter-Stemple-Str. 1, 86859 Igling, GERMANY

Facility Scopes:

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstr. 26, 86916 Kaufering, GERMANY

Design and Development, Production, Distribution, Installation and Servicing of Defibrillators, Patient Monitoring and Resuscitation Equipment including Accessories, External Battery Chargers and Power Supplies, Medical Software including Telemetry as well as Installation and Service Provision of Telemedical Software/Systems in the Cloud

REPs Facility ID: F009260

Date of Issue: 2026-09-23

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS

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

MDSAP
Medical Device Single Audit Program

TÜV SÜD

C E R T I F I C A T E

No. QS6 019931 0024 Rev. 00

GS Elektromedizinische Geräte G. Stemple GmbH
Günter-Stemple-Str. 1, 86859 Igling, GERMANY

Production, Installation, Distribution and Servicing of Defibrillators, Patient Monitoring and Resuscitation Equipment including Accessories, External Battery Chargers and Power Supplies

REPs Facility ID: F009281

Date of Issue: 2026-09-23

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS