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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

## No. G12 019931 0020 Rev. 00

**Manufacturer:**

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

SRN Manufacturer - DE-MF-000007648

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. 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:G12 019931 0020 Rev. 00

**Report No.:** 713262933

**Valid from:** 2024-05-08
**Valid until:** 2025-11-18

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2024-05-08


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

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## No. G12 019931 0020 Rev. 00

| | |
|---|---|
| **Classification:** | Class III |
| **Device Group:** | Z120305 - DEFIBRILLATORS |
| **Intended Purpose:** | - |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | ./. |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-05-08 | 713262933 | Initial issuance |


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