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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 019931 0018 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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 019931 0018 Rev. 00

Report No.: 713262933

Valid from: 2024-05-08
Valid until: 2029-05-07

Issue date: 2024-05-08

Christoph Dicks
Head of Certification/Notified Body

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

No. G70 019931 0018 Rev. 00

Classification:	Class III
Device Group:	Z120305 - DEFIBRILLATORS
Basic UDI-DI:	42601783500023J5
Intended Purpose:	The corpuls3 is intended • for measurement and monitoring of vital functions as well as • defibrillation, cardioversion or cardiac pacing of patients in the preclinical and clinical field by qualified medical staff trained in the use of the device. The following monitoring- and diagnostic functions are available: • ECG • Diagnostic ECG Optional: • Oximetry (SpO2) • Extended oximetry (SpCO®, SpHb, SpMet®) • Capnometry (CO2) • Temperature (Temp) • Non-invasive blood pressure monitoring (NIBP) • Invasive blood pressure monitoring (IBP) • CPR Feedback
Device(s):	04000 Base model corpuls3 04000.1 Base model corpuls3 NVG/NVIS 04001 Base model corpuls3 slim 04001.1 Base model corpuls3 slim NVG/NVIS 04002 Base model corpuls3 Touch 04002.1 Base model corpuls3 Touch NVG/NVIS 04003 Base model corpuls3 MAX 04003.1 Base model corpuls3 MAX NVG/NVIS 04004 Base model corpuls3 slim MAX 04004.1 Base model corpuls3 slim MAX NVG/NVIS 04005 Base model corpuls3 Touch MAX 04005.1 Base model corpuls3 Touch MAX NVG/NVIS

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No. G70 019931 0018 Rev. 00

Classification:	Class III
Device Group:	Z120305 - DEFIBRILLATORS
Basic UDI-DI:	42601783500022J3
Intended Purpose:	The corpuls3 is intended • for measurement and monitoring of vital functions as well as • defibrillation, cardioversion or cardiac pacing of patients in the preclinical and clinical field by qualified medical staff trained in the use of the device. The following monitoring- and diagnostic functions are available: • ECG • Diagnostic ECG Optional: • Oximetry (SpO2) • Extended oximetry (SpCO®, SpHb, SpMet®) • Capnometry (CO2) • Temperature (Temp) • Non-invasive blood pressure monitoring (NIBP) • Invasive blood pressure monitoring (IBP) • CPR Feedback
Device(s):	04100 Display Unit corpuls3 04101 Display Unit corpuls3 Touch 04101.1 Display Unit corpuls3 Touch NVG/NVIS 04100.1 Display Unit corpuls3

Classification:	Class III
Device Group:	Z120305 - DEFIBRILLATORS
Basic UDI-DI:	42601783500017JA
Intended Purpose:	The corpuls3 is intended • for measurement and monitoring of vital functions as well as • defibrillation, cardioversion or cardiac pacing of patients in the preclinical and clinical field by qualified medical staff trained in the use of the device. The following monitoring- and diagnostic functions are available: • ECG • Diagnostic ECG Optional: • Oximetry (SpO2) • Extended oximetry (SpCO®, SpHb, SpMet®) • Capnometry (CO2) • Temperature (Temp) • Non-invasive blood pressure monitoring (NIBP) • Invasive blood pressure monitoring (IBP) • CPR Feedback
Device(s):	04200 Patient Box corpuls3 04201 Patient Box corpuls3 Touch 04201.1 Patient Box corpuls3 Touch NVG/NVIS 04200.1 Patient Box corpuls3

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No. G70 019931 0018 Rev. 00

Classification:	Class III
Device Group:	Z120305 - DEFIBRILLATORS
Basic UDI-DI:	42601783500001HT
Intended Purpose:	The corpuls3 is intended • for measurement and monitoring of vital functions as well as • defibrillation, cardioversion or cardiac pacing of patients in the preclinical and clinical field by qualified medical staff trained in the use of the device. The following monitoring- and diagnostic functions are available: • ECG • Diagnostic ECG Optional: • Oximetry (SpO2) • Extended oximetry (SpCO®, SpHb, SpMet®) • Capnometry (CO2) • Temperature (Temp) • Non-invasive blood pressure monitoring (NIBP) • Invasive blood pressure monitoring (IBP) • CPR Feedback
Device(s):	04300 Defib Unit corpuls3 04301 Defib corpuls3 SLIM 04303 Defib corpuls3 MAX 04304 Defib corpuls3 SLIM MAX 04302 Defib corpuls3 Touch SLIM 04305 Defib corpuls3 Touch SLIM MAX 04300.1 Defib Unit corpuls3 04303.1 Defib corpuls3 MAX

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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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