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 Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 049076 0019 Rev. 00

Manufacturer:

Shenzhen Creative Industry Co., Ltd.
1001, Building West, Lepu Tower
No.66 Xingke Road, Xili Community
Xili Street, Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009430

Authorized Representative:

Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB Heerenveen, THE NETHERLANDS

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 049076 0019 Rev. 00

Report No.: GZ2315302
Valid from: 2026-02-13
Valid until: 2031-02-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-13

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

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Classification:	Class IIa
Device Group:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Classification:	Class IIb
Device Group:	Z12030202 - MULTI–PARAMETER PATIENT MONITORS
Intended Purpose:	Devices are used for monitoring vital physiological parameters.
Classification:	Class IIb
Device Group:	Z1203020292 - MULTI-PARAMETER MONITORS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	Central Monitoring System (hereinafter referred to as CMS) can work together with remote monitor the bedside patient monitors through cable LAN or WLAN to monitor simultaneously the physiological parameters, so as to perform central data monitoring, displaying, recording and printing.
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2026-02-13	GZ2315302	Initial issuance

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