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 (MDR)

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

No. G10 124103 0003 Rev. 00

Manufacturer:

LIFESURGE HEALTHCARE PRIVATE LIMITED
Plot Survey No.272, Rajpur - Katpur Road
Rajpur, Patan, Gujarat 384265
INDIA

SRN Manufacturer - IN-MF-000039135

Authorized Representative:

AF Pharma Service Europe SL
Muntaner 281, 08021 Barcelona, SPAIN

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 quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 124103 0003 Rev. 00

Report No.: TPS2689
Valid from: 2025-05-14
Valid until: 2030-05-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-05-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIa
Device Group:	A0101010102 - HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A020199 - SYRINGES, SINGLE-USE - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A03010101 - INFUSION CONTROLLERS WITH OR W/O AIR INLET
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A03010102 - INFUSION CONTROLLERS WITH FILTER (ALSO TRANSFUSION CONTROLLERS)
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A03020101 - LOW PRESSURE EXTENSION LINES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A03020102 - HIGH PRESSURE EXTENSION LINES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A03020199 - EXTENSIONS - OTHER
Intended Purpose:	-
Classification:	Class IIb
Device Group:	A03010104 - INFUSION MICRO-CONTROLLERS
Intended Purpose:	Measuring Volume set is a cylindrical container with capacity of 110 ml with a printed graduated scale with 1ml increments and 10ml overflow limit and it' is intended to control the volume of intravenous fluids in pediatric patients; short term use
Classification:	Class IIb
Device Group:	A03010104 - INFUSION MICRO-CONTROLLERS

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No. G10 124103 0003 Rev. 00

Intended Purpose: Measuring Volume set is a cylindrical container with capacity of 150 ml with a printed graduated scale with 1ml increments and 10ml overflow limit and it' is intended to control the volume of intravenous fluids in pediatric patients; short term use

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2025-05-14	TPS2689	Initial issuance

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