



EU Quality Management System Certificate

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

Certificate No. G15 120404 0003 Rev. 00

Manufacturer:

iLife Medical Devices Pvt Ltd

86, Sector-56, Phase-IV, IE Kundli
Sonapat, Haryana 131028
INDIA

SRN Manufacturer - IN-MF-000014372

**Authorized
Representative:**

CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N° 18, CP 29006 Málaga, SPAIN

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 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 120404 0003 Rev. 00

Report No.:

TPS1752

Valid from:

2025-09-30

Valid until:

2030-09-29

Issue date: 2025-09-30

Christoph Dicks
Head of Certification/Notified
Body



EU Quality Management System Certificate

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

Certificate No. G15 120404 0003 Rev. 00

Classification: Class IIa
Device Group: MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis

Classification: Class IIa
Device Group: MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

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

Revision History:

Rev.	Dated	Report	Description
00	2025-09-30	TPS1752	Initial issuance



Product Service

Confirmation Statement on device(s) covered by EU Quality Management System Certificate (MDR)

No. GRD 120404 0004 Rev. 00

Manufacturer: **iLife Medical Devices Pvt Ltd**
86, Sector-56, Phase-IV, IE Kundli
Sonepat, Haryana 131028
INDIA

This Confirmation Statement is only valid in combination with: G15 120404 0003 Rev. 00

This Confirmation Statement confirms device(s) covered by the aforementioned EU Quality Management System Certificate (MDR). It considers clarification of device(s) covered by the device group(s). For details and confirmation statement validity see:
www.tuvsud.com/ps-cert?q=cert:GRD 120404 0004 Rev. 00

Report No.: TPS1752

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2025-10-13

Confirmation Statement on device(s) covered by EU Quality Management System Certificate (MDR)**No. GRD 120404 0004 Rev. 00****Device(s):**

Sr.No	Medical Device Name
1	Intravenous Cannula/Catheter, Arterial Venous Cannula (with/ without safety feature)
2	Three Way Stop Cock (with / without Extension tube)
3	Extension Tube
4	Infusion Set
5	Blood Transfusion Set
6	Measure Volume Set