

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Sky Medical a.s.

Vicenzy, 24

SK – 931 01 Šamorín

has established and applies a quality management system
for the following scope:

Design, manufacturing, sterile packaging and sterilization of tubing sets, blood perfusion sets, tubing systems, accessories for fluid delivery and physiology pressure transducer sets. Packaging of medical components for third parties.

Design, manufacturing and packaging of bulk of tubing sets, blood perfusion sets, tubing systems, accessories for fluid delivery and physiology pressure transducer sets for third parties.

Manufacturing and packaging of medical thermoplastic and silicone catheters for third parties.

Through an Audit, Report No. 7974237010MT23, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0251902**.

This Certificate is valid from 2021-04-04 to 2024-04-03.

The reference date for all the next audits is (day-month): 22-03.

Milan, 2021-04-04. First Certification: 2018-04-04

The certification responsible: Cesare Gentile
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.



SGQ N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



Management System
EN ISO
13485:2016

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