

# 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. Design, manufacturing and packaging of medical components. Design, manufacturing and packaging of bulk of tubing sets, blood perfusion sets, tubing systems, accessories for fluid delivery and physiology pressure transducer sets. Consultancy services for medical device manufacturers.**

Through an Audit, Report No. 28113057-001, 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 2019-11-04 to 2021-04-03.

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

**Milan, 2019-11-04**, First Certification: 2018-04-04



The certification responsible: Massimiliano Testi  
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 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° 083A SGA N° 052D

Membro degli Accordi di Mutuo  
Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC  
Mutual Recognition Agreement

[www.tuvitalia.com](http://www.tuvitalia.com)

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