





Product Service

Certificate

No. Q6 098598 0001 Rev. 01

Holder of Certificate: ALLE S.R.L.

> Via Chizzalunga 1 36066 Sandrigo (VI)

ITALY

Certification Mark:



Production of infusion and irrigation sets for pump with accessories Scope of Certificate: and of sterile/non sterile medical devices such as gowns, drapes,

covers for operating theatre.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 098598 0001 Rev. 01

Report No.: ITA 2004218

Valid from: 2023-03-10 Valid until: 2026-03-09

Christoph Dicks Date, 2023-03-02

Head of Certification/Notified Body





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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): ALLE S.R.L.

Via Chizzalunga 1, 36066 Sandrigo (VI), ITALY

See Scope of Certificate