



Certificate

No. Q5 083085 0009 Rev. 03

Holder of Certificate: **Elcam Medical Italy S.p.A.**
Via Emilia Romagna 15
41012 CARPI (MO)
ITALY

Certification Mark:



Scope of Certificate: Design and development, manufacturing and sales of non-sterile, single-use molded, extruded and pre-assembled plastic components, as well as drug-delivery devices and assembled sets for the manufacturing of non-active medical devices.
Provision of contract manufacturing services for non-sterile, single-use molded or pre-assembled plastic components, as well as drug-delivery devices and assembled sets dedicated to fluid control.
Design and development, manufacturing and sales of sterile single-use accessories as non-active medical devices for infusion, transfusion and hemodialysis.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 083085 0009 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_083085_0009_Rev_03)

Report No.: ITA200220015923

Valid from: 2026-10-01
Valid until: 2029-09-30

Date, 2026-07-31

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Elcam Medical Italy S.p.A.**
Via Divisione Acqui 26, 41037 MIRANDOLA (MO), ITALY

Provision of contract manufacturing services for non-sterile, single-use, pre-assembled or assembled sets dedicated to fluid control. Manufacturing of non-sterile, single-use extruded, pre-assembled plastic components as well as non-sterile assembled sets for non-active medical devices manufacturing.

Elcam Medical Italy S.p.A.
Via Emilia Romagna 15, 41012 CARPI (MO), ITALY

Design and development, manufacturing and sales of non-sterile, single-use molded and pre-assembled plastic components, as well as drug-delivery devices for the manufacturing of non-active medical devices.

Provision of contract manufacturing services for non-sterile, single-use molded, pre-assembled plastic components and drug-delivery devices for medical device manufacturing.

Design and development, manufacturing and sales of sterile single-use accessories as non-active medical devices for infusion, transfusion and hemodialysis.

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