



# Certificate

No. Q5 083085 0009 Rev. 02

**Holder of Certificate:** **Elcam Medical Italy S.p.A.**

Via Emilia Romagna 15  
41012 CARPI (MO)  
ITALY

**Certification Mark:**



**Scope of Certificate:**

**Design, production and sales of molded and pre-assembled plugs, connectors, spikes and caps, and non-active finished medical devices for infusion, transfusion and haemodialysis. The provision of manufacturing services for non-active infusion and transfusion systems, nutrition bags, drainage bags, urology sets, haemodialysis lines and external circulating devices for blood, molded and pre-assembled components for medical device manufacturing.**

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 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:Q5 083085 0009 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_083085_0009_Rev.02)

**Report No.:** ITA2060006

**Valid from:** 2023-10-01

**Valid until:** 2026-09-30

**Date,** 2023-09-14



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

The provision of manufacturing services for non-active infusion and transfusion systems, nutrition bags, drainage bags, urology sets, haemodialysis lines and external circulating devices for blood.  
Production of preassembled connectors, spikes and caps for medical devices manufacturing.

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

Design, production and sales of molded and pre-assembled plugs, connectors, spikes, caps, non -active finished medical devices for infusion, transfusion and haemodialysis.  
The provision of manufacturing services for molded and pre-assembled components for medical device manufacturing.

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