



Certificate

No. Q5 083085 0009 Rev. 01

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

Via Emilia Romagna 15
41012 CARPI (MO)
ITALY

Facility(ies):

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

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

Certification Mark:



Scope of Certificate:

Design, production and distribution of haemodialysis blood lines and accessories, infusion and transfusion sets and accessories, tubular systems, molded and pre-assembled components for medical devices manufacturing. Production for third parties of infusion and transfusion systems, nutrition bags, drainage bags, urology sets, haemodialysis lines and external circulating devices for blood.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: ITA1461092

Valid from: 2020-10-01

Valid until: 2023-09-30

Date, 2020-07-31

Christoph Dicks
Head of Certification/Notified Body