



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
267354-2018-AQ-ITA-ACCREDIA

Initial certification date:
03 August 2015

Valid:
01 August 2024 – 31 July 2027

This is to certify that the management system of
COMEF S.r.l. Società a socio unico
Via Giovanni XXIII - 41012 Carpi (MO) - Italy

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

Production by injection molding and automatic, semiautomatic and manual assembly and distribution of plastic components for single use medical devices on customer-defined applications such as dialysis, infusion, transfusion, extra-bodily circulation and other surgical applications

Place and date:
Vimercate (MB), 23 July 2024



SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F

EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento
SGQ, SGA, PRD, PRS, ISP, GIG, LAB e LAT, di MLA IAF
per gli schemi di accreditamento SGQ, SGA, SSI, FSM
e PRD e di MRA ILAC per gli schemi di accreditamento
LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) -
Italy

Claudia Baroncini
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Business Assurance Italy S.r.l., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 039 68 99 905. www.dnv.it