



EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 083085 0013 Rev. 00

Manufacturer: Elcam Medical Italy S.p.A.

Via Emilia Romagna 15 41012 CARPI (MO)

ITALY

Facility(ies): Elcam Medical Italy S.p.A.

Via Emilia Romagna 15, 41012 CARPI (MO), ITALY

Elcam Medical Italy S.p.A.

Via Divisione Acqui 26, 41037 MIRANDOLA (MO), ITALY

Product Category(ies): Accessories for transfusion and haemodialysis (plugs, connectors, spikes, caps)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid from: 2019-10-17 **Valid until:** 2024-05-26

Date, 2019-10-17

Stefan Preiß

1. Punil

Head of Certification/Notified Body