



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 036310 0041 Rev. 00

Manufacturer:

Securmed S.p.A.

Via Monte Grappa, 2G 36016 Thiene (VI)

ITALY

Facility(ies):

Securmed S.p.A.

Viale Piane Nocella, 23, 64012 Campli (Teramo), ITALY

Product

Category(ies):

Urethral catheters, cannula and tube for surgical suction, rectal catheters, enteral feeding tubes, duodenal tubes, suction catheters, devices for oxygen respiratory therapies (oxygen catheters, nasal oxygen cannula, oxygen connecting tubes, oxygen masks, tracheostomy masks, aerosol masks, nebulizers), drainage systems

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

Report No.:

ITA1279445

Valid from: Valid until: 2019-08-08 2024-05-26

Date,

2019-08-08

Stefan Preiß

1. Punil

Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123