



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 004962 0001 Rev. 00

Manufacturer: GALBIATI 1935 srl

Via Umbria 10 20090 Segrate (MI)

ITALY

Facility(ies): GALBIATI 1935 srl

Via Umbria 10, 20090 Segrate (MI), ITALY

Product Category(ies): Dental unit with accessories

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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 2023-11-15

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Stefan Preiß

1. Pumil