



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Product Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex VI
(Devices in Class I with measuring function)

No. G3M 044963 0031 Rev. 01

Manufacturer:

Fazzini s.r.l.

SS Padana Sup. 317
20090 Vimodrone (MI)
ITALY

Facility(ies):

Fazzini s.r.l.
SS Padana Sup. 317, 20090 Vimodrone (MI), ITALY

Product Category(ies):

Aneroid Sphygmomanometers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and testing of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report no.:

ITA1466063

Valid from:

2020-04-03

Valid until:

2024-05-26

Date,

2020-04-03

Christoph Dicks
Head of Certification/Notified Body



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Product Service

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 044963 0034 Rev. 01

Manufacturer:

Fazzini s.r.l.

SS Padana Sup. 317
20090 Vimodrone (MI)
ITALY

Product Category(ies): Patient Monitor, Fetal and Maternal Monitor,
Electrocardiographs, Pulse Oximeters

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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