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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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.

**Report No.:** ITA1466063

**Valid from:** 2020-04-03

**Valid until:** 2024-05-26

**Date,** 2020-04-03

Christoph Dicks  
Head of Certification/Notified Body