



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 15 03 65300 001

Manufacturer: **BTS S.P.A.**
Via della Croce Rossa, 11
35129 Padova
ITALY

Facility(ies): **BTS S.P.A.**
Via della Croce Rossa, 11, 35129 Padova, ITALY

BTS S.P.A.
Via Forlanini, 40, 20024 Garbagnate Milanese (MI), ITALY

Product Category(ies): **Medical devices for motion analysis, electromyographs**

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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Hans-Heiner Junker

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

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