



Product Service

EC - CERTIFICATE

Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 05 12 55450 003

Manufacturer: Fedegari Autoklaven AG

Via Alla Gerra, 11
6930 Bedano (TI)
SWITZERLAND

Facility(ies):

Fedegari Autoklaven AG
Via Alla Gerra, 11, 6930 Bedano (TI), SWITZERLAND

**Product
Category(ies):**

**Moist- heat sterilizers for
Medical devices**

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

Report No.: ITA147099

Valid until: 2010-12-07



Date, 2005-12-29

Reiner Krumme

TÜV Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.



Product Service

CERTIFICATE

No. Q2N 05 12 55450 002

Holder of Certificate: Fedegari Autoklaven AG

Via Alla Gerra, 11
6830 Bedano (TI)
SWITZERLAND

Facility(ies):

Fedegari Autoklaven AG
Via Alla Gerra, 11, 6930 Bedano (TI), SWITZERLAND

Certification Mark:



Scope of Certificate: Production and servicing
of Moist-heat Sterilizers

**Applied
Standard(s):**

EN ISO 13485: 2003
Medical Devices-
Quality Management Systems-
Requirements for regulatory purposes

The Certification Body of TÜV Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA147099

Valid until: 2008-11-30



Date, 2005-12-29

Reiner Krumme