CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証書 ◆ CERTIFICATE ◆ CERTIFIKAT

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.

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TÜV SÜD 249560

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.