

Certificate

Production Quality Assurance System Approval Annex V of the Directive on Medical Devices

ECM, Eifelstr. 1c, 52068 Aachen, notified to EC under **0481** hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Transatlantic Handelsgesellschaft Stolpe & Co. mbH

Am Joseph 8-10, D-61273 Wehrheim

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

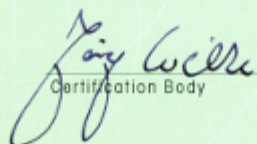
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Date of initial certification: 2001-10-29

Prolongation: 2007-12-21

Report Number	Registered under	Valid until
120-07-102	Z/07/01462	2012-12-21

Aachen, 2007-12-21


Certification Body



Akkreditiert durch
Zustellstelle der Länder
für Gesundheitsberufe
und Apotheken
ZL 5-ZG-925.94.05