

Certificate

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

ECM, Bismarckstr.106, 52066 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

HMT Medizintechnik GmbH
Frauenstrasse 30, D-82216 Maisach

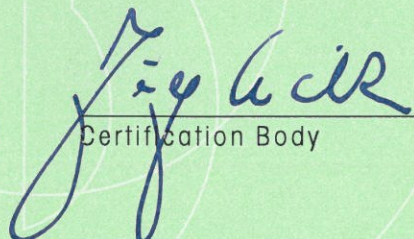
ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

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.

Report Number	Registered under	Valid until
020-10-310	Z/11/02434	March 28 th , 2016

Aachen, March 28th, 2011


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08



Benannt durch/Designated by
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www.zlg.de
ZLG-BS-240.10.12

Annex I to Certificate Z/11/02434

Number of Pages: 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use device	Heart-Lung Bypass Unit Tubing Sets	15-012
Single use device	Cardioplegia Solution Administration Kits	16-163
Single use device	Irrigation/Distention Systems, Arthroscopic	17-233
Single use device	Heat Exchangers, Regional Perfusion	13-318
Single use device	Filters, Hemoconcentration	17-598
Single use device	Tubes, Connecting	14-188
Single use device	Tubing Set to lead in gas (Distension System)	/

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.

¹ UMDNS Code is optional