Certificate

Production Quality Assurance System Approval

Annex V of the Directive on Medical Devices

ecm

ECM 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

MEDINORM Medizintechnik
GmbH
Stiftstr. 4, D-66287 Quierschied

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
Z011-001	Z/02/00391	18.03.2006

Aachen, 2002-11-21

Lead Auditor

Certification Body

Annex I to Certificate Z/02/00391

Number of Pages: 1

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Single use devices	Intravenous Line connectors	18-066
Single use devices	Aspirators, Tracheal	10-219
Single use devices	Cement Dispensers, Orthopedic	16-472
Single use devices	Bowls, Mixing, Cement	17-221
Single use devices	Tubes, Feeding, Nasoenteral	16-798
Single use devices	Tubing, Suction	16-779
Single use devices	Catheters, Urethral	10-762
Single use devices	Clamps, Umbilical	10-876
Single use devices	Catheters, Other	15-209
Single use devices	Catheters, Rectal	10-746
Single use devices	Catheters, Nelaton	10-734
Single use devices	Catheters, Nasal Oxygen	12-702
Single use devices	Drains, Wound	11-305
Single use devices	Aspirators, Surgical	10-217
Single use devices	Drains, Sump	15-270
Single use devices	Drainconnector	--
Single use devices	Catheterplug	--
Single use devices	Fingertip	--
Single use devices	Catheterization Kits, Cardiac	10-598
Single use devices	Anesthesia Kits, Epidural	10-127
Single use devices	Anesthesia Kits, Spinal	10-131
Single use devices	Catheter Sets, urological	--

Special terms of validity:

None.

[1] GMDNS Code is optional