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 undermentioned 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

Gewerbepark 7-9; 66583 Spiesen Elversberg, Germany

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.

The approved quality assurance system is subject to periodic surveillance as defined by Annex V, section 4.

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
147-19-64	**Z/19/04575E**	**July 15th, 2024**

Valid as of: July 16th, 2019

Certification Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I to Certificate Z/19/04575E

Number of Pages: 1 of 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 devices	Aspirators, Tracheal	10-219
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, 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	Drain Connector	--
Single use devices	Catheter Plug	--
Single use devices	Fingertip	--
Single use devices	Autotransfusion Units, Whole Blood Recovery	17-538
Single use devices	Cannulae, Other	15-206

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