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

Temena GmbH
Mittelhöfer Straße 1, 34587 Felsberg Gensungen, 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
007-18-58	**Z/18/04251E**	**June 16th, 2023**

Valid as of: July 5th, 2018

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/18/04251E

Number of Pages: 1 of 1

ecm
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	Drainage Systems, Pleural	10-817
Single use devices	Cannulae, Epidural	10-572
Single use devices	Syringes	13-929
Single use devices	Fittings/Adapters, Luer	11-729
Single use devices	Catheters, Spinal, Epidural, Anesthetic	16-430
Single use devices	Sterile Procedure Packs (Article 12 MDD)	/
Single use devices	Needles, Anesthesia	12-733
Single use devices	Cannulae	10-561
Single use devices	Cannulae, Eye	10-573
Single use devices	Catheters, Vascular, Infusion, Central Venous	10-729
Single use devices	Catheters, Vascular, Umbilical	10-759
Single use devices	Filters	11-710

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