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

PakuMed Medical Products GmbH
Im Löwental 79; 45239 Essen, 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
373-17-316	Z/17/04126E	October 22nd, 2022

Aachen, October 23rd, 2017

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/17/04126E

Date of revision: February 17th, 2020
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	Nomencloture code[1]
Single use devices	Needles, Subcutaneous Injection/Infusion Port	17-180
Single use devices	Trocars	14-154
Single use devices	Sterile procedure packs (Article 12 MDD)	/
Single use devices	Catheterization Kits	15-564
Single use devices	Retractors, Vessel	13-393
Single use devices	Fittings/Adapters, Luer	11-729

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