Certificate

EC Design Examination

Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.4 of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

PakuMed Medical Products GmbH
Im Löwental 79, 45239 Essen

ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 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 examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number	Registered under	Valid until
373-08D7A9	Z/18/04218E	January 25th, 2022

Valid as of: April 18th, 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 of Certificate Z/18/04218E

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]
Non-active implantable products	Catheters, others KA PU 7.5F KA PU 9F KA PU 5.15F KA PU 5,5 F-A KA PU 3 F KA PU G23 KA SI 8F1 KA PU 10 F	15-209

Special terms of validity:

None.

[1] UMDNS Code ist optional