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

Vygon GmbH & Co. KG

Prager Ring 100, 52070 Aachen, 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.

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
001-16-927	Z/16/03965E	November 12th, 2021

Aachen, November 13th, 2016

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/16/03965E

Number of Pages: 1 of 2

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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	Catheterization Kits, Central Venous	16-615
Single use devices	Catheter, Central Venous, Peripherally Inserted	18-017
Single use devices	Catheter, Hemodialysis	15-022
Single use devices	Catheter, others	15-209
Single use devices	Adhesive, liquid	10-036
Single use devices	Catheters, Vascular, Umbilical	10-759
Single use devices	Catheters, Spinal, Epidural	10-717
Single use devices	Fittings/Adapters, Luer	11-729
Single use devices	Fittings/Adapters, Pneumatic, Other	16-797
Single use devices	Guide Wires	11-925
Single use devices	Guides, Other	15-224
Single use devices	Intravenous Line Connectors, Needleless	18-066

[1] UMDNS Code is optional

Annex I to Certificate Z/16/03965E

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Single use devices	Cables/Leads, ECG	15-754
Single use devices	Catheter Introducers-Hemostasis Valve	17-578
Single use devices	Catheter Introducers	10-678
Single use devices	Ports, Vascular Access	16-858
Single use devices	Catheters, Vascular, Microflow	10-691
Single use devices	Catheters, Vascular, Embolectomy/Thrombectomy	10-714
Single use devices	Tubing, Polyvinyl Chloride	14-247
Single use devices	Transfer Sets, Fluid	16-610

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