Certificate

Full Quality Assurance System Approval

Annex II excluding (4) 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 II excluding (4) 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 full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

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 II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number	Registered under	Valid until
001-17-1127	**Z/17/04150E**	**December 19th, 2022**

Aachen, December 19th, 2017

Certification Body

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

Digitally signed by Grabazei Alexandru
Date: 2025.06.26 12:45:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANA

Annex I of Certificate Z/17/04150E

Date of revision: May 25th, 2020

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*
Single use devices	Adhesive, liquid -- siliconeglue	10-036
Single use devices	Catheter Introducers -- specanula -- splitneedle -- peelable cannula -- microsite	10-678
Single use devices	Catheters, Arterial Micro-Flow -- leaderflex	10-691
Single use devices	Catheters, Vascular, Embolectomy / Thrombectomy -- embolectoball	10-714
Single use devices	Catheters, Spinal, Epidural -- peristyl -- peripur	10-717
Single use devices	Catheters, Vascular, Umbilical -- umbilicalcath expert -- umbilicalcath2 expert -- umbilicalcath3	10-759
Single use devices	Fittings / Adapters, Luer -- easylock -- transadapt	11-729
Single use devices	Guide Wires -- guide	11-925

* UMDS Code is optional

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	Tubing, Polyvinyl Chloride -- Extension line -- Verlängerungs-Katheter	14-247
Single use devices	Catheter Hemodialysis -- dualysecath -- trilysecath -- dualysecathexpert -- trilysecathexpert -- lifecath twin	15-022
Single use devices / Non active implantable products	Catheter Hemodialysis -- lifecath apheresis+ -- lifecath apheresis	15-022
Single use devices	Catheters, others -- repairset lifecath	15-209
Single use devices	Guides, Other -- introducath desilet -- desivalve	15-224
Single use devices	Cables/Leads, ECG -- combcard	15-754

[1] UMDS Code is optional

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*
Single use devices	Transfer Sets, Fluid -- Taky-Spike - Plus -- Transfer-Set -- Iectrocath	16-610
Single use devices	Catheterization Kits, Central Venous -- seldipur -- multicath2 -- multicath3 -- multicath4 -- multicath5 -- multicath7 -- leadercathexpert -- multicath2expert -- multicath3expert -- multicath4expert -- multicath5expert -- multicath7expert -- lifecath broviac -- lifecath hickman -- lifecath biflux -- lifecath triple -- lifecath broviac expert -- lifecath hickman expert -- lifecath biflux expert -- multistar2 -- multistar3 -- multistar4 -- multistar5 -- multistar7	16-615

* UMDS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code*
Single use devices	Catheters, Cardiac, Flotation Balloon, Pacing Electrodes -- bipacingball	16-654
Single use devices	Catheter Introducers -- aseptcath	17-578
Single use devices	Catheter, Central Venous, Peripherally Inserted -- premicath -- epicutaneo cava pur -- lifecath PICC expert -- epicutaneo2expert -- epicutaneo cava expert -- epicutaneo cava -- epicutaneo2 -- epicutaneostar -- epicutaneo2star -- premistar -- lifecath PICC silicone -- nutriline -- nutriline twinflo -- nutristar -- nutristar twinflo	18-017

* UMDS Code is optional

Annex I of Certificate Z/17/04150E

Date of revision: May 25th, 2020

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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 / Non active implantable products	Catheter, Central Venous, Peripherally Inserted -- lifecath PICC pur -- lifecath PICC easy -- lifecath CT PICC easy -- maxflo -- maxfloexpert	18-017
Single use devices	Intravenous Line Connectors, Needleless -- repairset epicutaneo cava	18-066
Single use devices	Catheters, Vascular, Infusion, Peripheral --seldipur smartmidline -- homecarecathexpert -- lifecath midline pur	10-727
Single use devices	Cables/Leads, ECG vygocard	15-754

Special terms of validity:

None.

[1] UMDS Code is optional