Certificate

Production Quality Assurance System Approval
Annex V of the Directive on Medical Devices

ecm

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

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, 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
218-15-2018	Z/15/03696E	November 17th, 2020

Aachen, November 18th, 2015

Certification Body

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de

ZLG-BS-240.10.12

Digitally signed by Iarovoi Petru
Date: 2019.02.01 16:58:30 EET
Reason: MoldSign Signature
Location: Moldova

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Annex I to Certificate Z/15/03696E
Number of Pages: 1 of 1

ecm

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Single use devices	Fittings, Adapter	11-726
Single use devices	Drainage Systems, Pleural	10-817
Single use devices	Drains, Thoracic	11-308
Single use devices	Guide Wires	11-925
Single use devices	Catheters, Introducers	10-678
Single use devices	Catheters, Vascular, Blood Pressure	10-689
Single use devices	Catheters, Vascular, Embolectomy/Thrombectomy	10-714
Single use devices	Catheters, Cardiac, Pericardium Drainage	10-741
Single use devices	Catheters, Others	15-209
Single use devices	Catheters, Rinsing	10-730
Single use devices	Catheters, Vascular, Embolectomy/Thrombectomy, Ballon, Venous	10-756
Single use devices	Tubing, Suction	16-779
Single use devices	Strippers, Vein	13-828
Single use devices	Tubes, Bronchial	15-322
Single use devices	Tubes, Connecting	14-188
Single use devices	Valves	14-325
Single use devices	Manifolds	15-587
Single use devices	Catheters, Vascular, Infusion, Central Venous	10-729
	Sterile Procedure Packs acc. §12, MDD	
Single use devices	Casework, General-Purpose	15-896
	Sterile Procedure Packs acc. §12, MDD	

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. • REPUBLICA MOLDOVA, mun. CHIȘINĂU • Sogno S.R.L. IDNO 1004600013954

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

UMDNS Code is optional

Certificate

Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical Devices

ecm

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

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, 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.

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
218-15-1028	Z/15/03701E	November 29th, 2020

Aachen, November 30th, 2015

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/15/03701E
Page 1 of 1

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	16-654
Single use devices	Catheters, Cardiac, Flotation Balloon, Pulmonary Artery, Thermal Dilution	10-754

Special terms of validity:

None.

UMDS Code is optional

Certificate

EC Design Examination
Annex II.4 of the Directive on Medical Devices

ecm

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

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, Deutschland

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
218-09425E 218-092FA9	Z/15/03702E	November 29th,2020

Aachen, November 30th, 2015

Certification Body

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de

ZLG-BS-240.10.12

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Single use devices	Catheters, Cardiac, Flotation Balloon, Pacing Electrodes Intrastim -- 022 244M -- 022 245M -- 022 246M -- 052 225M -- 052 225	16-654
Single use devices	Catheters, Cardiac, Flotation Balloon, Pulmonary Artery, Thermal Dilution Intrathermodin -- Thermodilution Catheter -- 440 115 -- 440 116 -- 440 117 -- 450 117 -- Pulmonary Artery Monitoring Catheter -- 250 115 -- 250 116 -- 250 117 -- 252 116 -- 252 117	10-754

Special terms of validity:

None.

[1] UMDNS Code ist optional