Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.

Through an audit performed on behalf of

ANDOCOR n.v.
Kwikaard 104, 2980 Zoersel, Belgium

it could be demonstrated that a quality management system

according to **DIN EN ISO 13485:2016**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **design, manufacturing and sales of medical devices for cardiovascular surgery and anaesthesia: Sterile cardiovascular cannulation devices, Sterile cardioplegia devices, Sterile bloodlines for hemoconcentration with or without hemofilters, Sterile gas diffusers**

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report mentioned hereafter. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
771-19-19	Z/19/04489E	March 31st, 2022

Digitally signed by Captari Alexandru
Date: 2020.06.10 19:24:54 EEST
Reason: MoldSign Signature
Location: Moldova

Valid as of: April 01st, 2019

Certification Body

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

ANDOCOR n.v.

Kwikaard 104, 2980 Zoersel, Belgium

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
771-16-54	Z/16/03836E	June 19th, 2021

Aachen, June 20th, 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 of Certificate Z/16/03836E

Date of revision: December 13th, 2018

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]
single use devices	Arterial Cannula, reinforced	34893
single use devices	Arterial Cannula, non-reinforced	34893
single use devices	Aortic Catheter	34893
single use devices	Venous Catheter	34905
single use devices	Flex Line Venous Catheter	34905
single use devices	Two Stage Venous Catheter	34905
single use devices	Flex Line Two Stage Venous Catheter	34905
single use devices	Vent Catheters	46363
single use devices	Pericardial Sump	35917
single use devices	Rigid Sucker	35917
single use devices	Intracardiac Suckers	35917
single use devices	Yankauer Suction Tubes	35917
single use devices	Suction connecting tubes	16779
single use devices	Aspiration tubes	16779
single use devices	Vent Plugs	/
single use devices	Vented Connector Caps	/
single use devices	Vessel Cannulae	47798
single use devices	Connectors	61661
single use devices	Extremity Perfusion Cannulae	/

[1] Generic Term is optional

Annex I of Certificate Z/16/03836E

Date of revision: December 13th, 2018

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]
single use devices	Cannulation Tourniquet Set	58830
single use devices	Quick Prime Line	47889
single use devices	Tubing Organizer	/
single use devices	Pressure Monitoring Line	61836
single use devices	Aortic Root Cannulae	47799
single use devices	Retrograde Cardioplegia Cannula	36109
single use devices	Cardioplegia Set	58824
single use devices	Cardioplegia Needle	47799
single use devices	Ostial Perfusion Cannulae	34896
single use devices	Gas Diffuser	42977
single use devices	Hemoconcentrators	44602
single use devices	Hemoconcentrator Tubing Sets	44602
single use devices	Set for haemoconcentration	44602

Special terms of validity:

None.

[1] Generic Term is optional

ANDOCOR

CARDIOVASCULAR CANNULATION PRODUCTS

REINFORCED, CURVED TIP WITH FLANGE

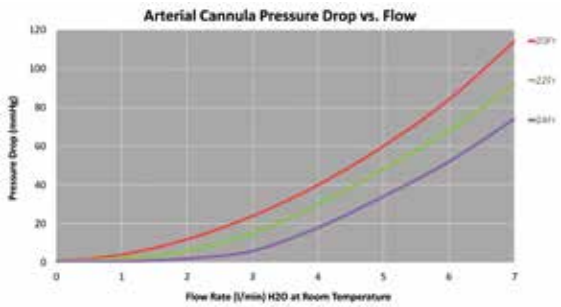
ARTERIAL CANNULAE

Andocor arterial cannulae are intended for perfusion of the ascending aorta during cardiopulmonary bypass.

DETAILS	
Connection site	3/8”
Qty/box	20 Pcs

Features & Benefits

- ✓ Kink resistant reinforced tubing
- ✓ Easy tip orientation thanks to indexing marker
- ✓ Smooth plastic tip



	SIZE	LENGTH	WITHOUT VENT PLUG/ RED CAP	WITH VENT PLUG	WITH VENTED RED CAP	LENGTH	WITHOUT VENT PLUG/ RED CAP	WITH VENT PLUG	WITH VENTED RED CAP
WITHOUT CONNECTOR	20 Fr	33cm	A2016	A2016V		24 cm	B2016	B2016V	
	22 Fr	33cm	A2216	A2216V		24 cm	B2216	B2216V	
	24 Fr	33cm	A2416	A2416V		24 cm	B2416	B2416V	
WITH CONNECTOR	20 Fr	33cm	A20161		A20161V	24 cm	B20161		B20161V
	22 Fr	33cm	A22161		A22161V	24 cm	B22161		B22161V
	24 Fr	33cm	A24161		A24161V	24 cm	B24161		B24161V
WITH LUER CONNECTOR	20 Fr	33cm	A20162		A20162V	24 cm	B20162		B20162V
	22 Fr	33cm	A22162		A22162V	24 cm	B22162		B22162V
	24 Fr	33cm	A24162		A24162V	24 cm	B24162		B24162V

CARDIOVASCULAR CANNULATION PRODUCTS

REINFORCED, STRAIGHT TIP WITH RING

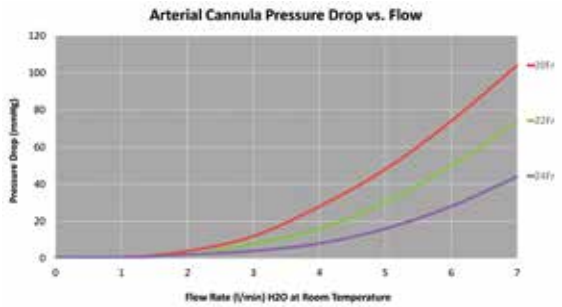
ARTERIAL CANNULAE

Andocor arterial cannulae are intended for perfusion of the ascending aorta during cardiopulmonary bypass.

DETAILS	
Connection site	3/8”
Qty/box	20 Pcs

Features & Benefits

- ✓ Kink resistant reinforced tubing
- ✓ Easy tip orientation due to indexing marker
- ✓ Smooth plastic tip



	SIZE	LENGTH	WITHOUT VENT PLUG/ RED CAP	WITH VENT PLUG	WITH VENTED RED CAP	LENGTH	WITHOUT VENT PLUG/ RED CAP	WITH VENT PLUG	WITH VENTED RED CAP
WITHOUT CONNECTOR	20 Fr	33 cm	A2013	A2013V		24 cm	B2013	B2013V	
	22 Fr	33 cm	A2213	A2213V		24 cm	B2213	B2213V	
	24 Fr	33 cm	A2413	A2413V		24 cm	B2413	B2413V	
WITH CONNECTOR	20 Fr	33 cm	A20131		A20131V	24 cm	B20131		B20131V
	22 Fr	33 cm	A22131		A22131V	24 cm	B22131		B22131V
	24 Fr	33 cm	A24131		A24131V	24 cm	B24131		B24131V
WITH LUER CONNECTOR	20 Fr	33 cm	A20132		A20132V	24 cm	B20132		B20132V
	22 Fr	33 cm	A22132		A22132V	24 cm	B22132		B22132V
	24 Fr	33 cm	A24132		A24132V	24 cm	B24132		B24132V

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