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: 2020.04.25 18:12:54 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

REINFORCED WITH LIGHTHOUSE TIP

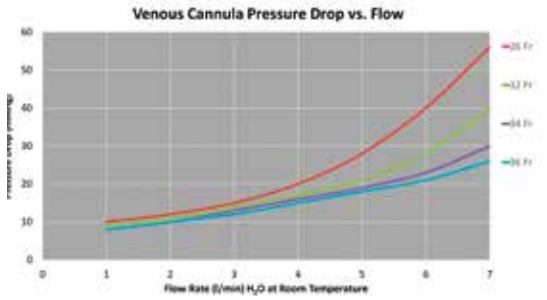
FLEX LINE VENOUS CANNULAE

Andocor venous cannulae are intended to drain venous blood from the right atrium and caval veins.

DETAILS	
Length	39 cm
Qty/box	20 Pcs

Features & Benefits

- ✓ Single piece construction
- ✓ Open and flexible lighthouse tip
- ✓ Easy positioning
- ✓ Insertion depth marker



SIZE	STRAIGHT TIP	RIGHT ANGLED 90° TIP	CONNECTION SITE
20 Fr	01V201L8	01V201L9	3/8”
22 Fr	01V221L8	01V221L9	3/8”
24 Fr	01V241L8	01V241L9	3/8”
26 Fr	01V261L8	01V261L9	3/8”
28 Fr	01V281L8	01V281L9	3/8”
30 Fr	01V301L8	01V301L9	3/8”
32 Fr	01V321L8	01V321L9	3/8”
34 Fr	01V341L8	01V341L9	3/8”
36 Fr	01V361L8	01V361L9	1/2”

SIZE	NON-REINFORCED	CONNECTION SITE
32 Fr	VC3208	3/8”

BALLOON TIP

DETAILS	
Length	30 cm
Qty/box	20 Pcs

CODE	BALLOON SIZE	TIP SIZE
OC06A	6 mm	3 mm
OC07A	7 mm	3 mm

Features & Benefits

- ✓ Self-inflating silicone balloon
- ✓ Female luer lock connection

BASKET TIP

OSTIAL PERFUSION CANNULAE

Andocor ostial perfusion cannulae are intended for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

DETAILS	
Length	21 cm
Qty/box	20 Pcs

Features & Benefits

- ✓ Basket tip
- ✓ Different configurations
- ✓ Malleable stainless steel shaft

	TIP SIZE	CODE
WITH 45° TIP	10 Fr	OC1045
	12 Fr	OC1245
	14 Fr	OC1445
WITH 90° TIP	10 Fr	OC1090
	12 Fr	OC1290
	14 Fr	OC1490