

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.

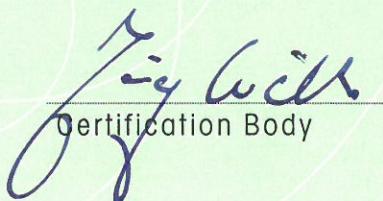
This certificate is only valid under the conditions stated in the audit report mentioned hereafter. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number
771-19-19

Registered under
Z/19/04489E

Valid until
March 31st, 2022

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
771-16-54

Registered under
Z/16/03836E

Valid until
June 19th, 2021

Aachen, June 20th, 2016


Certification Body



Annex I of Certificate Z/16/03836E

Page 1 of 2

Date of revision: December 13th, 2018



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

Page 2 of 2

Date of revision: December 13th, 2018



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.

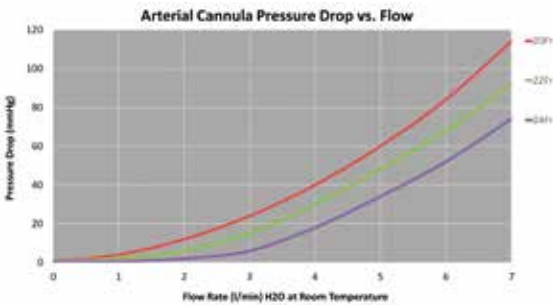


DETAILS	
Connection site	3/8"
Qty/box	20 Pcs



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 WITH LIGHTHOUSE TIP

FLEX LINE VENOUS CANNULAE

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

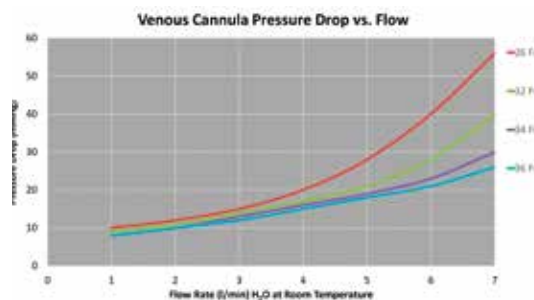
DETAILS

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"

CARDIOVASCULAR CANNULATION PRODUCTS



PROXIMAL AND DISTAL REINFORCED WITH LIGHTHOUSE TIP

FLEX LINE TWO STAGE VENOUS CANNULAE

Andocor two stage venous cannulae are intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.



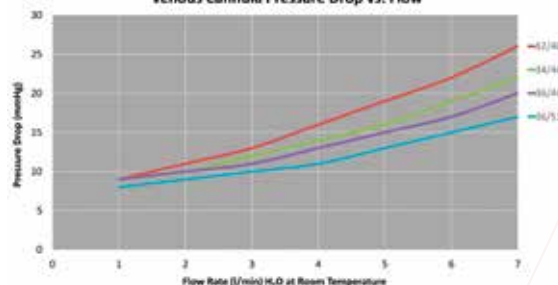
Features & Benefits

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

DETAILS

Connection site	1/2"
Length	40 cm
Qty/box	20 Pcs

Venous Cannula Pressure Drop vs. Flow



	SIZE	STANDARD BODY	FLAT BODY
WITHOUT CONNECTOR	32/40 Fr	01V32L40	01V32L40FB
	34/46 Fr	01V34L46	01V34L46FB
	36/46 Fr	01V36L46	01V36L46FB
	36/51 Fr	01V36L51	01V36L51FB
WITH CONNECTOR	32/40 Fr	01V32L401	01V32L401FB
	34/46 Fr	01V34L461	01V34L461FB
	36/46 Fr	01V36L461	01V36L461FB
	36/51 Fr	01V36L511	01V36L511FB
WITH LUER CONNECTOR	32/40 Fr	01V32L402	01V32L402FB
	34/46 Fr	01V34L462	01V34L462FB
	36/46 Fr	01V36L462	01V36L462FB
	36/51 Fr	01V36L512	01V36L512FB

BALLOON TIP



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

DETAILS	
Length	30 cm
Qty/box	20 Pcs



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

SUCKERS

ANDOCOR



PERICARDIAL SUMPS

Andocor suckers are used for the removal of excess fluid from the surgical field.



Features & Benefits

- ✓ Smooth and flush design
- ✓ Weighted tip
- ✓ Drainage of pericardial sack

DETAILS

Connection site	1/4"
Qty/carton	20 Pcs



PS40M | PS40ML | PS40MLH



PS40M1

METAL TIP

CODE	DESCRIPTION	TUBING LENGTH	EXTERNAL DIAMETER TIP
PS40M	METAL TIP	36 cm	6 mm
PS40ML	LONG TUBING	80 cm	6 mm
PS40MLH	LONG, HARD TUBING	80 cm	6 mm
CODE	DESCRIPTION	TUBING LENGTH	EXTERNAL DIAMETER TIP
PS40M1	LARGE METAL TIP	36 cm	7,8 mm

WIREWOUND TIP



DETAILS

Code	PS40
Size	16 Fr
Length	36 cm
Qty/box	20 Pcs

HEMOCONCENTRATORS



HEMOCONCENTRATORS

Andocor hemoconcentration filters are intended to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase concentrations of cells and proteins in the blood.



Features & Benefits

- ✓ Pre-rinsed or non-rinsed filters
- ✓ Standard or custom-made blood lines

DESCRIPTION	FILTERS	CODE	QTY/BOX
HEMOCONCENTRATOR HC0250	NON-RINSED PRE-RINSED	03HC0250 03HP0250	10 Pcs
HEMOCONCENTRATOR HC0600	NON-RINSED PRE-RINSED	03HC0600 03HP0600	6 Pcs
HEMOCONCENTRATOR HC1000	NON-RINSED PRE-RINSED	03HC1000 03HP1000	6 Pcs
TUBING SET		03HCS001	40 Pcs

TECHNICAL FEATURES

	HC0250	HC0600	HC1000
INTENDED USE	PAEDIATRIC	ADULT	ADULT
MEMBRANE AREA	0.25 m ²	0.6 m ²	1.0 m ²
PRIMING BLOOD VOLUME	18 ml	51 ml	76 ml
MAX. TRANS-MEMBRANE PRESSURE	500 mmHg	500 mmHg	500 mmHg
UNIT LENGTH	180 mm	180 mm	265 mm
ULTRAFILTRATION RATE AVERAGE KUF IN VIVO 22 ml/h/mmHg/m ²	5.5	13.2	22.0