

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.

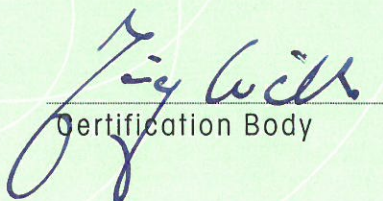
This certificate is only valid under the conditions stated in the audit report mentioned hereafter. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

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

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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