Digitally signed by Captari Alexandru
Date: 2019.03.14 09:13:43 EET
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Location: Moldova

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
ZLG-BS-240.10.12

S.R.L. «CAVATEH M»

Annex I of Certificate Z/16/03836E

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
single use devices	Arterial Cannula, reinforced	35565
single use devices	Arterial Cannula, non-reinforced	35565
single use devices	Aortic Catheter	35565
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	10685
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	/
single use devices	Extremity Perfusion Cannulae	/

S.R.L. „CAVATEH M."

Generic Term is optional

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
single use devices	Cannulation Tourniquet Set	/
single use devices	Quick Prime Line	/
single use devices	Tubing Organizer	/
single use devices	Pressure Monitoring Line	/
single use devices	Aortic Root Cannulae	47799
single use devices	Retrograde Cardioplegia Cannula	36109
single use devices	Cardioplegia Set	47799
single use devices	Cardioplegia Needle	47799
single use devices	Ostial Perfusion Cannulae	34896
single use devices	Gas Diffuser	44484
single use devices	Hemoconcentrators	44602
single use devices	Hemoconcentrator Tubing Sets	44602
single use devices	Set for haemoconcentration	44602

Special terms of validity:

None.

S.R.L. „CAVATEH M."

Generic Term is optional

Certificate

Quality Assurance

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 9001:2008. Through an audit performed on behalf of

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

it could be demonstrated that a quality assurance system

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

according to **DIN EN ISO 9001:2008**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. 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
771-16-54	Z/16/03838E	June 19th, 2019

Aachen, June 20th, 2016

Certification Body

S.R.L. CAVATEH M.

Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2012.

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 13485:2012**
"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 cardioplegio 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 hereafter mentioned audit report. 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
771-16-54	Z/16/03837E	June 19th, 2019

Aachen, June 20th, 2016

Certification Body

S.R.L. CAVATEH M.