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**

Valid as of: April 01st, 2019

Certification Body