Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1429047-1

Certificate Holder: Ferris Mfg. Corp.

5133 Northeast Parkway Fort Worth TX 76106

USA

Scope: Design and Development, Manufacture, and Distribution of

Wound Care Dressings

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.:
 234206759-31

 Effective date:
 2023-12-24

 Expiry date:
 2026-12-23

 Issue date:
 2023-12-12

Replaces certificate SX 1429047-1 issued on 2022-02-20

This certificate can be validated on https://www.certipedia.com

Dipl.-Ing. Sebastiano Pane TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany





CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Artivion Inc.

Scope of certification:

Design and development, production and distribution of implantable medical devices, cardiovascular bovine pericardial patches, surgical adhesives and surgical accessories.

Installation and servicing of surgical laser equipment:

Distribution of surgical adhesives and accessories, cardiovascular patches, mechanical heart valve prostheses and accessories, stentgrafts and stentgraft systems, vascular prostheses for the treatment of aortic and peripheral vessels, aortic dissection stents, and interventional accessories

Certified location:

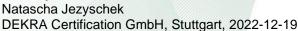
1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, USA (further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51523-R1-00.

Certificate registration no.: 51523-14-00 Certificate valid f

Certificate valid from: 2022-12-19
Certificate valid to: 2025-12-18







Annex to the Certificate No. 51523-14-00

valid from 2022-12-19 to 2025-12-18

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Artivion Inc.	1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144 USA	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.	Artivion, Inc.	2140, Barrett Park Drive, Kennesaw 30144 Georgia USA	Storage of raw materials and finished good
2.	Cryolife Europa Ltd.,	Old Portsmouth Road Guildford, Surrey GU3 1LR, Great Britain	Distribution of surgical adhesive and accessories, cardiovascular patches, and medical devices for the treatment of vascular and cardiovascular diseases
3.	JOTEC GmbH	Lotzenäcker 23 72379 Hechingen Germany	Distribution of surgical adhesive and accessories, cardiovascular patches, and medical devices for the treatment of vascular and cardiovascular diseases





CERTIFICATE



This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6 75177 Pforzheim Germany

has implemented and maintains a Quality Management System.

Scope:

Design and Development, Manufacturing, Sales and Final Control of Product Categories Catheters, Stents, Stent Delivery Systems and endovascular Medical Devices for neurosurgical cardiological and peripheral Applications.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07

EN ISO 13485 : 2016 + AC : 2016

ISO 13485: 2016

Certificate registration no. 516802 MP2016

Certificate unique ID 170774421

Effective date 2021-06-19

Expiry date 2024-06-18

Frankfurt am Main 2021-04-28

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

1. Mb luca

Sigrid Uhlemann Managing Director Dr. Thomas Feldmann Head of Certification Body



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