CERTIFICATE

Number: 2144088

The management system of the organization(s) and locations mentioned on the addendum belonging to:

GELITA MEDICAL GmbH

Uferstrasse 7
69412 Eberbach
Germany

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
Design and development, manufacture and distribution of sterile absorbable hemostats and bulk sterile or non-sterile absorbable hemostats for surgical applications.

Certificate expiry date: 1 December 2024
Certificate effective date: 1 December 2021
Certified since: 7 April 2011

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 2144088

The management system of the organization(s) and/or location(s) of:

GELITA MEDICAL GmbH

Uferstrasse 7
69412 Eberbach
Germany

Certified organization(s) and/or locations:	Different scope
GELITA AG Gammelsbacher Strasse 2 69412 Eberbach	Design and development, manufacture and distribution of sterile absorbable hemostats and bulk sterile or non-sterile absorbable hemostats for surgical applications.
GELITA AG Uferstrasse 7 69412 Eberbach	Design and development, manufacture and distribution of sterile absorbable hemostats and bulk sterile or non-sterile absorbable hemostats for surgical applications.

Addendum expiry date: 1 December 2024
Addendum effective date: 1 December 2021

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

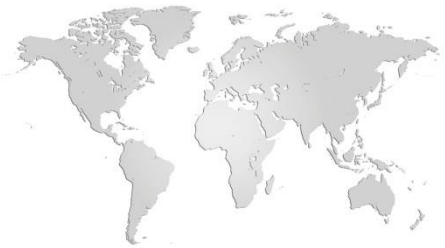
This certificate can be validated on https://www.certipedia.com

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565 Stuttgart

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-12-19

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

Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-12-19

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

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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