Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 19 din 01.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- BioGlue® Surgical Adhesive

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.09.29 16:30:28 EEST
Reason: MoldSign Signature
Location: Moldova

Data 01.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- BioGlue® Surgical Adhesive

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 01.10.2023

ARTIVION
Formerly CryoLife | Jotec
artivion.com

EU DECLARATION OF CONFORMITY

according to *Annex IV of the Medical Device Regulation (EU) 2017/ 745*

Manufacturer's Name:	Artivion, Inc. (formerly CryoLife)
SRN:	US-MF-000015763
Business Address:	1655 Roberts Blvd, NW Kennesaw, Georgia 30144 United States of America
Authorized European Representative:	Jotec GmbH
SRN:	DE-AR -000006801
Business Address:	Lotzenäcker 23 72379 Hechingen, Germany
Object of this Declaration:	BioGlue® Surgical Adhesive (See Attachment #1)
Intended Purpose/ Indications for Use:	BioGlue® Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, and/or patches) to adhere, seal, and/ or reinforce soft tissue. Indicated soft tissues are cardiac, vascular, pulmonary, and dural.
Classification:	Class III, according to 2017/745 Annex VIII, Chapter III, Rules 8 (long-term surgically invasive implantable device intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and have a biological effect or are wholly or mainly absorbed) and 18 (utilizes tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable)
MDR Codes:	Design and intended purpose: MDN 1101 Specific characteristics: MDS 1001, MDS 1005 Technologies or processes: MDT 2008, MDT 2009, MDT 2011
Notified Body:	DEKRA Certification GmbH, Handwerkstr. 15, 70565 Stuttgart, Germany, ID No. 0124
Conformity Assessment Route(s):	Annex IX of the MDR, assessment of Full Quality Assurance System and Technical Documentation

Artivion, Inc., herewith declares under sole responsibility that the above-mentioned medical devices are in accordance with all applicable requirements of the Medical Device Regulation (EU)

2017/745. In addition, the BioGlue Surgical Adhesive implant material meets the requirements of EU Regulation 722/2012.

This declaration was issued based on the Full Quality Assurance Certificate No. 51523-60-00 issued 19-Dec-2022 and EC Certificate No. 51523-61-A0 issued 19-Dec-2022.

Standards applied to the medical device. (See Attachment #2)

Authorized Signatory:

DocuSigned by Drew Green
Drew Green | I approve this document
22-Dec-2022 | 4:02:15 PM EST
A52E56718B4A430FA51BC60A79362F48

22-Dec-2022

Drew Green
Vice President, Regulatory Affairs
Artivion, Inc.
Kennesaw, Georgia, USA

Date

Artivion, Inc.
1655 Roberts Blvd, NW, Kennesaw, GA 30144

ARTIVION
Formerly CryoLife | Jotec
artivion.com

Attachment 1

BioGlue® Surgical Adhesive
Declaration of Conformity Schedule of Product Codes
Revision Date: December 22, 2022

Product Code	Description of Product	Basic UDI-DI	GMDN Code	CND Code
BG3502-5-G	5 Pack, BioGlue Surgical Adhesive Syringes, 2 mL	87723400BG35007W	47784[1]	H90010101[2]
BG3510-5-G	5 Pack, BioGlue Surgical Adhesive Syringes, 10 mL			
BG3515-5-G	5 Pack, BioGlue Surgical Adhesive Syringes, 5 mL			

[1] GMDN 47784, Surgical internal adhesive/sealant, animal-derived: A bioabsorbable substance containing animal-derived material [e.g., bovine serum albumin (BSA)/cross-linking agent] intended to be used for internal surgical applications to bond or seal cut, incised, or resected body tissues (e.g., for vascular anastomosis) typically as an adjunct to standard methods of closure, to seal leaks, and might in addition be intended to achieve haemostasis through tissue sealing. Disposable mixing devices/applicators may be included for preparation and application to anatomical sites. After application, this device cannot be reused.
[2] CND H90010101, Tissue Glues, Biological

Artivion, Inc.
1655 Roberts Blvd, NW, Kennesaw, GA 30144

Attachment 2

Standards Applied

Standard	Title
EN ISO 13485:2016	Medical devices - Quality management system requirements for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
EN ISO 22442-2:2020	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling
EN ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
MEDDEV 2.7.1, Rev 4	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.12.1, Rev 8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12.2, Rev 2	Guidelines on Post Market Clinical Follow-Up
ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 10993-1:2018	Biological Evaluation of Medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2006	Biological Evaluation of Medical devices – Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological Evaluation of Medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2017	Biological Evaluation of Medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological Evaluation of Medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological Evaluation of Medical devices – Part 6: Tests for local effects after implantation
ISO 10993-9:2019	Biological Evaluation of Medical devices – Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10:2010	Biological Evaluation of Medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological Evaluation of Medical devices – Part 11: Tests for systemic toxicity
ISO 10993-17:2002	Biological Evaluation of Medical devices – Part 17: Methods for the establishment of allowable limits for leachable substances
ISO/TS 10993-20:2006	Biological Evaluation of Medical devices – Part 20: Principles and methods for immunotoxicology testing of

Artivion, Inc.
1655 Roberts Blvd, NW, Kennesaw, GA 30144

Standard	Title
	medical devices
ISO 11137-1:2006/AMD 2:2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
ISO 11737-1:2018	Sterilization of health care products- Microbiological Methods - Part 1: Determination of a population of microorganisms on products
ANSI/AAMI/ISO 11737-2:2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
GHTF/SG3/N99-10:2004	Quality Management Systems - Process Validation Guidance
BS EN ISO 14630:2012	Non-active surgical implants – General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices. AMD: October 31, 2013
ISO 15223-1:2021	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements
ASTM F2503-20	Standard practice for marking Medical Devices and other items for Safety in the Magnetic Field
ISO 11607-1:2019	Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging system
ISO 11607-2:2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
ANSI/AAMI ST72:2019	Bacterial Endotoxins- Test Methods, Routine Monitoring, and Alternatives to Batch Testing
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Artivion, Inc.
1655 Roberts Blvd, NW, Kennesaw, GA 30144

EU Certificate

for the assessment of the technical documentation

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter II

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

Artivion Inc.

Single Registration Number (SRN): US-MF-000015763
1655 Roberts Boulevard NW, 30144 Kennesaw, USA

Name, address of the authorized representative:
Jotec GmbH Lotzenäcker 23, 72379 Hechingen, Germany

that the technical documentation of the product(s) described in the annex complies with the provisions of the Medical Device Directive (EU) 2017/745. The certificate is based on the results of the assessment of the technical documentation according to the Medical Devices Regulation (EU) 2017/745 Annex IX Chapter II, which are recorded in the report referred to in the annex.

Product: BioGlue® Surgical Adhesive

EU Certificate no.: 51523-61-A0

Certificate valid from: 2022-12-19
Certificate valid to: 2027-12-18

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565 Stuttgart

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-12-19
Notified Body ID number: 0124

Annex to the EU Certificate no. 51523-61-A0

valid from 2022-12-19 to 2027-12-18

Revision status of the annex: 0 dated 2022-12-19

Report Number: 51523-TD1-04

Product: BioGlue® Surgical Adhesive

Basis-UDI-DI: 87723400BG35007W

Risk Classification: Class III

Intended Use:

BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, and/or patches) to adhere, seal, and/or reinforce soft tissue. Indicated soft tissues are cardiac, vascular, pulmonary, and dural.

Technical Data:

5 Pack, BioGlue Surgical Adhesive Syringes, 2 mL	BG3502-5-G
5 Pack, BioGlue Surgical Adhesive Syringes, 10 mL	BG3510-5-G
5 Pack, BioGlue Surgical Adhesive Syringes, 5 mL	BG3515-5-G

Remark: For the placing on the market of the product(s) referred to above, an additional EU certificate for the assessment of the quality management system in accordance with Annex IX Chapter I is required.

Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-12-19
Notified Body ID-number: 0124