MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
257642-2018-AQ-CZE-NA-PS

Initial certification date:
11 April 2019

Valid:
12 April 2022 – 11 April 2025

This is to certify that the management system of

BIOSINTEX S.R.L.

4 Vladiceasca Str., RO 077168, Snagov, Ilfov County, Romania

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, development, manufacturing, sales and distribution of sterile surgical sutures, with/ without needles.

Digitally signed by Dubalari Pavel
Date: 2022.10.06 10:51:17 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 30 March 2022

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 17 October 2019

For: DNV GL Presafe AS

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **13422-2018-CE-CZS-NA-PS Rev 2.0**

Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	Change of product name	2019-09-11
2.0	**Editorial change** **BICRIL changed to DACRIL** **BICRIL RAPID changed to DACRIL RAPID** **BICRIL 910 changed to DACRIL 910**	**2019-10-17**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
13422-2018-CE-CZS-NA-PS Rev 2.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that:

Sterile surgical sutures

Manufactured by:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 17 October 2019

For: DNV GL Presafe

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	Change of product name	2019-09-11
2.0	**Editorial change** **BICRIL changed to DACRIL** **BICRIL RAPID changed to DACRIL RAPID** **BICRIL 910 changed to DACRIL 910**	**2019-10-17**

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**
Sterile surgical sutures	III

Short description of the Medical Device:

Surgical sutures with or without needle.

DACRIL - Polyglycolic acid multifilament coated, absorbable
DACRIL RAPID - Polyglycolic acid multifilament coated, fast absorbable
DACRIL 910 - Poly(glycolide-co-Lactide) (90/10) multifilament coated, absorbable
PDO-x- Polydioxanone monofilament, absorbable
MONO-x- Poly(glycolide-co-caprolactone) (75/25) monofilament, absorbable
BIOPRO- Polypropylene monofilament, non-absorbable

All the sutures are sterilized by Ethylene Oxide.

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000409145-PA-NA-CZE Rev. 2.0	PRJC-595657-2019-PRC-CZE	01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.

4 Vladiceasca Str. 077168 Snagov, Romania

For design, production and final product inspection/testing of:

STERILE SURGICAL SUTURES

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 02 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate Removing of HERNIPRO Polypropylene Meshes and Prosthesis. Previously in the certificate N.:11713-2017-CE-NA-PS rev.1.0	13 October 2020
1.0	Editorial change	13 October 2020
2.0	**Reintroduced old device names (covered by 11713-2017-CE-NA-PS Rev. 1.0 until 2020-03-11) NYLON MULTI and NYLON MONO**	**02 November 2020**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile surgical sutures	BIOSTER Polyester suture multifilament synthetic coated non-absorbable	IIb
	BIOSILK Silk suture multifilament natural coated non-absorbable	
	BIONIL MULTIx & **NYLON MULTI** Polyamide (tip 6.6) suture multifilament synthetic coated non-absorbable	
	BIONIL MONOx & **NYLON MONO** Polyamide (tip 6.6) suture monofilament synthetic non-absorbable	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

Certificate No.:	Project No.:	Valid Until:
10000409145-PA-NA-CZE Rev. 2.0	PRJC-595657-2019-PRC-CZE	01 November 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Address: 4th Vlădiceasca St., Snagov, Ilfov County, Romania, 077168
VAT number: RO14779017; Reg. Number: J40/6627/2002

EC DECLARATION OF CONFORMITY No. 1

Manufacturer Manufacturer's address	BIOSINTEX SRL 4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, monofilament absorbable made of polydioxanone with and without needles.
Type	**PDOx**
Classification	The devices are classified as ***class III*** according the rule 8c of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **PDOx** -*Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 15 April 2022

ROXANA BUSCU
Quality Manager

Address: 4th Vlădiceasca St., Snagov, Ilfov County, Romania, 077168
VAT number: RO14779017; Reg. Number: J40/6627/2002

EC DECLARATION OF CONFORMITY No. 2

Manufacturer Manufacturer's address	BIOSINTEX SRL 4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, monofilament absorbable made of poly(glycolide-co-caprolactone) (75/25) (PGCL)with and without needles.
Type	**MONOx**
Classification	The devices are classified as ***class III*** according the rule 8c of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **MONOx** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS.
Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 15 April 2022

ROXANA BUSCU
Quality Manager

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Email: contact@biosintex.com;
Web: www.biosintex.com

Address: 4th Vlădiceasca St., Snagov, Ilfov County, Romania, 077168
VAT number: RO14779017; Reg. Number: J40/6627/2002

EC DECLARATION OF CONFORMITY No. 3.1

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, monofilament non-absorbable made of polyamide (nylon 6,6) with and without needles.
Type	**BIONIL MONOx**
Classification	The devices are classified as ***class IIb*** according the rule 8 of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II excluding section 4 of the Medical Device Directive 93/42/EEC amended by 2007/47/EC.

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices:
BIONIL MONOx - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 29 April 2022

ROXANA BUSCU
Quality Manager

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BioSintex
LEADING SURGICAL SUTURE

Address: 4th Vlădiceasca St., Snagov, Ilfov County, Romania, 077168
VAT number: RO14779017; Reg. Number: J40/6627/2002

EC DECLARATION OF CONFORMITY No. 3.2

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament non-absorbable made of polyamide (nylon 6,6) with and without needles.
Type	**BIONIL MULTIx**
Classification	The devices are classified as ***class IIb*** according the rule 8 of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II excluding section 4 of the Medical Device Directive 93/42/EEC amended by 2007/47/EC.

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices:
BIONIL MULTIx - *surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 29 April 2022

ROXANA BUSCU
Quality Manager

Phone/Fax: +4021 266 00 01; +4021 266 00 02
Email: contact@biosintex.com;
Web: www.biosintex.com

Address: 4th Vlădiceasca St., Snagov, Ilfov County, Romania, 077168
VAT number: RO14779017; Reg. Number: J40/6627/2002

EC DECLARATION OF CONFORMITY No. 4

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament non-absorbable made of polyester with and without needles.
Type	**BIOSTER**
Classification	The devices are classified as ***class IIb*** according the rule 8 of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II excluding section 4 of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **BIOSTER** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 29 April 2022

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Quality Manager

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EC DECLARATION OF CONFORMITY No. 5

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament non-absorbable made of silk with and without needles.
Type	**BIOSILK**
Classification	The devices are classified as ***class IIb*** according the rule 8 of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II excluding section 4 of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **BIOSILK -** *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 29 April 2022

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EC DECLARATION OF CONFORMITY No. 7

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament absorbable made of polyglycolic acid with and without needles.
Type	**DACRIL**
Classification	The devices are classified as ***class III*** according the rule 8c of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **DACRIL** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway **Notified Body 2460**

Bucharest, 15 April 2022

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BioSintex
LEADING SURGICAL SUTURE

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EC DECLARATION OF CONFORMITY No. 8

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament absorbable made of polyglycolic acid, fast absorbable with and without needles.
Type	**DACRIL RAPID**
Classification	The devices are classified as ***class III*** according the rule 8c of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **DACRIL RAPID** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS.
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Bucharest, 15 April 2022

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EC DECLARATION OF CONFORMITY No. 9

Manufacturer	BIOSINTEX SRL
Manufacturer's address	4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, multifilament absorbable made of poly(glycolide-co-Lactide)(90/10)(PGLA) with and without needles.
Type	**DACRIL 910**
Classification	The devices are classified as ***class III*** according the rule 8c of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **DACRIL 910** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS.
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Bucharest, 15 April 2022

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EC DECLARATION OF CONFORMITY No. 10

Manufacturer Manufacturer's address	BIOSINTEX SRL 4thVladiceasca St., Snagov, Ilfov County, Romania
Medical Device(s)	Surgical sutures, sterile, monofilament non-absorbable made of polypropylene with and without needles.
Type	**BIOPRO**
Classification	The devices are classified as class III according the rule 8b of the Annex IX of the Medical Device Directive 93/42/EEC amended by 2007/47/EC
Conformity assessment route	Full Quality Assurance, according Annex II of the Medical Device Directive 93/42/EEC amended by 2007/47/EC

BIOSINTEX SRL, as manufacturer, declares under sole responsibility that medical devices: **BIOPRO** - *Sterile surgical sutures with/without needle* related to this declaration fulfills the Annex 1 – Essential Requirements of Medical Devices Directive 93/42/EEC amended by 2007/47/EC.
The object of the declaration described above is in conformity with the requirements of the following standards:

EN ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2012	*Medical devices – Application of risk management to medical devices*
EN ISO 11135-1:2007	*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2006 EN ISO 11737-1:2006/AC:2009	*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-3:2014	*Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
EN ISO 10993-4:2009	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-6:2009	*Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
EN ISO 10993-7:2008 EN ISO 10993-7:2008/AC:2009	*Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
ISO 10993-10:2010	*Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
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*
EN 62366:2008	*Medical devices – Application of usability engineering to medical devices*

Notified Body: The conformity evaluation was performed with participation of DNV Product Assurance AS.
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