BioSintex
LEADING SURGICAL SUTURE

Adresa: Str. Vlădiceasca, nr. 4, Snagov, Jud. Ilfov, România, 077168
Cod fiscal: RO14779017; Reg. Com: J40/6627/2002

SC BIOSINTEX SRL
INTRARE
IEŞIRE Nr. 956
Ziua 19 Luna 04 Anul 2021

Către toți cei interesați

Ne face plăcere să vă anunțăm că am demarat actualizarea Declarațiilor de Conformitate pentru dispozitivele noastre medicale.

Actualizarea survine ca urmare a schimbării numelui Organismului Notificat responsabil pentru certificarea dispozitivelor noastre din DNV GL Presafe AS (NB2460) in DNV Product Assurance AS (NB2460).

Atașat aveți prima serie a Declarațiilor de Conformitate actualizate emise în data de 16.04.2021, aferente dispozitivelor medicale de clasa III:

DoC_No.1 PDO'x
DoC_No.2 MONO'x
DoC_No.7 DACRIL
DoC_No.8 DACRIL RAPID
DoC_No.9 DACRIL 910
DoC_No.10 BIOPRO

Rămânem la dispoziția dumneavoastră pentru orice întrebări suplimentare.

To all interested parties

We are pleased to announce you that we have started the updating of the Declarations of Conformity for our medical devices.

The update occurs as a result of name changing of the Notified Body responsible for the certification of our devices from DNV GL Presafe AS (NB2460) to DNV Product Assurance AS (NB2460).

Attached you have the first series of updated Declarations of Conformity issued on 16.04.2021, related to class III medical devices:

DoC_No.1 PDO'x
DoC_No.2 MONO'x
DoC_No.7 DACRIL
DoC_No.8 DACRIL RAPID
DoC_No.9 DACRIL 910
DoC_No.10 BIOPRO

We will remain at your disposal for any further questions.

19.04.2021

Alin Iosif
Director General

SOCIETATEA COMERCIALA 15 BIOSINTEX S.R.L. RO14779017 BUCUREȘTI ROMÂNIA

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Date: 2021.12.04 11:19:37 EET
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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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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, 16 April 2021

ROXANA BUSCU
Quality Manager

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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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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, 16 April 2021

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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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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**

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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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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*

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Bucharest, 16 April 2021

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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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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*

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ROXANA BUSCU
Quality Manager

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:

ISO 9001:2015	*Quality management systems - Requirements*
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 11737-2:2009	*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 10993-11:2009	*Biological evaluation of medical devices —Part 11: Tests for systemic toxicity*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*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*

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