

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 633494**

Issued To:

**Internacional Farmacéutica, S.A. de C.V.
Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Mexico**

In respect of:

Design, development and manufacture of sterile absorbable and non-absorbable surgical sutures, partially absorbable surgical meshes, bone wax and temporary epicardic pacing wire.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-11-29**Date: **2020-10-23**Expiry Date: **2024-05-26**

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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 633494

Issued To:

Internacional Farmacéutica, S.A. de C.V.
Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Mexico

Number	Device Name	Intended purpose per IFU
Class III		
---	Atramat® PGC25 Poly(glycolide-co -epsilon-caprolactone) Absorbable Surgical Sutures	See CE 633645
---	Atramat® PGLA90 Polyglactin 910 Poly(glycolide-co-L-lactide) Absorbable Surgical Sutures	See CE 633647
---	Atramat® PGLA90 RAPID Polyglactin 910 Poly(glycolide-co-L- lactide) Quick Absorption Surgical Sutures	See CE 633649
---	Atramat® PGA (Polyglycolic Acid) Absorbable Surgical Suture	See CE 633653
---	Atramat® PGA RAPID (Polyglycolic Acid) Quick Absorption Surgical Suture	See CE 633667
---	Atramat® PDX (Polydioxanone) Absorbable Surgical Sutures	See CE 633668
---	Atramat® PVDF (Polyvinylidene Fluoride) Surgical Sutures	See CE 633671
---	Atramat® Polypropylene Surgical Suture	See CE 633672
---	Atramat® Polyester Surgical Suture	See CE 633673
---	Atramat® TEMPORARY EPICARDIC PACING WIRE	See CE 633674
---	Atramat PROPYMESH Flex® Synthetic Partially Absorbable Surgical Mesh	See CE 633675

First Issued: **2015-11-29**

Date: **2020-10-23**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 633494

Issued To:

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Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Mexico

Class IIb		
GMDN Code	Device Name	Intended purpose per IFU
15971	Atramat® Stainless Steel Surgical Sutures	The Atramat® Stainless Steel surgical suture is indicated for orthopedic use, as well as in surgical procedures that require a high-resistance, artificial support, such as sternum closure (sternotomy), all in accordance with acceptable surgical procedures and techniques used for non-absorbable sutures. Atramat® Stainless Steel surgical suture to be used depends on the patient's general condition, the surgeon's surgical experience/technique, and the type of wound to be closed.
38000	Atramat® Nylon Surgical Sutures	The Nylon Atramat® surgical suture is indicated to be used in approach and/or general ligation of soft tissues in general, as well as for ophthalmic procedures and microsurgery. It must be used according to the acceptable surgical procedures and techniques used for non-absorbable sutures, taking into account the place of its application. The Nylon Atramat® surgical suture to be used will depend on the overall condition of the patient, the surgeon's experience, the surgical technique and the wound to be closed.

First Issued: **2015-11-29**

Date: **2020-10-23**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 633494

Issued To:

Internacional Farmacéutica, S.A. de C.V.
Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Mexico

Class IIb		
GMDN Code	Device Name	Intended purpose per IFU
13910	Atramat® Silk Surgical Sutures	The Atramat® Silk surgical suture is indicated for use in approach and/or general ligation of soft tissues in general, as well as for ophthalmic procedures. It must be used according to the acceptable surgical procedures and techniques used for non-absorbable sutures, taking into account the place of its application. The Atramat® Silk surgical suture to be used will depend on the overall condition of the patient, the surgeon's experience, the surgical technique and the wound to be closed.
46930	Atramat® Bone Wax	The Atramat® Bone Wax is used to control the bleeding of bone surfaces, acting by physical tamponade of the bone canals. Once open, the Atramat® Bone Wax should be softened by the use of an aseptic technique until the desirable consistency is achieved, which will be applied to the bone surface if required in the surgical procedure or if the surgeon prefers.

First Issued: **2015-11-29**

Date: **2020-10-23**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EB Sertifikatas - visiško kokybės užtikrinimo sertifikavimo patvirtinimas
pagal medicinos prietaisų direktyvą 93/42/EEB, II priedas išskyrus 4 skirsnį.

Nr. CE633494
Išduota: **International Farmaceutica, S.A. de C.V.**
Carreteraco Nr. 44
Caolonia Parque San Andres
Coyoacan
C.P. 04040
Ciudad de Meksika
Meksika

Suinteresuotiems asmenims:

Sterilių besirezorbuojančių ir nesirezorbuojančių chirurginių siūlų, nesirezorbuojančių ir dalinai besirezorbuojančių chirurginių tinklelių, kaulų vaško ir laikinų epikardo stimuliacijos vielų kūrimas, vystymas ir gamyba.

Remiantis kokybės užtikrinimo sistemos patikrinimu pagal Tarybos direktyvos 93/42/EEB II priedo reikalavimus, išskyrus 4 skirsnį. Kokybės užtikrinimo sistema atitinka direktyvos reikalavimus. Pateikiant į rinką III klasės gaminius, reikalingas II priedo 4 skirsnio pažymėjimas.

Minėtos direktyvos notifikuojoji įstaiga BSI vardu ir jos vardu (notifikuotosios įstaigos numeris 2797):

/Parašas/

Gary E Slack, Vyresnysis medicinos prietaisų viceprezidentas

Pirmas leidimas: 2015-11-29

Data: 2020-10-23

Galioja iki: 2024-05-26

EB Sertifikatas - visiško kokybės užtikrinimo sertifikavimo patvirtinimas

papildoma sertifikato informacija CE 633494

Nr. **CE633494**
 Išduota: **International Farmaceutica, S.A. de C.V.**
Carreteraco Nr. 44
Caolonia Parque San Andres
Coyoacan
C.P. 04040
Ciudad de Meksika
Meksika

Numeris	Produkto pavadinimas	Paskirtis pagal anudojimosi instrukciją
III klasė		
---	Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) tirpūs/besirezorbuojantys chirurginiai siūlai	Žr. CE 633645
---	Atramat® PGLA90 Poliglaktino 910 Poly(glycolide-co-L-lactide) tirpūs/besirezorbuojantys chirurginiai siūlai	Žr. CE 633647
---	Atramat® PGLA90 RAPID Poliglaktino 910 Poly(glycolide-co-L-lactide) tirpūs/greitai besirezorbuojantys chirurginiai siūlai	Žr. CE 633649
---	Atramat® PGA (Poliglikolio rūgštis) tirpūs/besirezorbuojantys chirurginiai siūlai	Žr. CE 633653
---	Atramat® PGA RAPID (Poliglikolio rūgštis) tirpūs/greitai besirezorbuojantys chirurginiai siūlai	Žr. CE 633667
---	Atramat® PDX (Polidioksanono) tirpūs/besirezorbuojantys chirurginiai siūlai	Žr. CE 633668
---	Atramat® PVDF (Polivinilidenfluorido) chirurginiai siūlai	Žr. CE 633671
---	Atramat® Polipropileno chirurginiai siūlai	Žr. CE 633672
---	Atramat® Poliesterio chirurginiai siūlai	Žr. CE 633673
---	Atramat® LAIKINOS EPIKARDO STIMULIACIJOS VIELOS	Žr. CE 633674
---	ATRAMAT PROPYEMESH® Polipropileno monofilamento chirurginis tinklas	Žr. CE 633675

Pirmas leidimas: **2015-11-29**Data: **2020-10-23**Galioja iki: **2024-05-26**

EB Sertifikatas - visiško kokybės užtikrinimo sertifikavimo patvirtinimas

papildoma sertifikato informacija CE 633494

Nr. **CE633494**
 Išduota: **International Farmaceutica, S.A. de C.V.**
Carreteraco Nr. 44
Caolonia Parque San Andres
Coyoacan
C.P. 04040
Ciudad de Meksika
Meksika

IIb klasė		
GMDN kodas	Produkto pavadinimas	Paskirtis pagal naudojimosi instrukciją
---	Atramat® Nerūdijančio plieno chirurginiai siūlai	Atramat® Nerūdijančio plieno chirurginiai siūlai yra skirti ortopedijos reikmėms, taip pat atliekant chirurgines procedūras, kurioms reikalingas didelis atsparumas, dirbtinė atrama, pvz., krūtinkaulio uždarymas (sternotomija), visa tai atitinka priimtinas chirurgines procedūras ir metodus, naudojamus neįsisavinamiems siūlams. Atramat® Nerūdijančio plieno chirurginių siūlų naudojimas priklauso nuo paciento bendros būklės, chirurgo chirurginės patirties/technikos ir uždaromos žaizdos tipo.
---	Atramat® Nailono (poliamido) chirurginiai siūlai	Atramat® Nailono (poliamido) chirurginiai siūlai yra naudojami taikant ir (arba) apskritai perrišant minkštuosius audinius, taip pat oftalmologinėms procedūroms ir mikro chirurgijoje. Siūlai turi būti naudojami pagal priimtinas chirurgines procedūras ir metodus, naudojamus nesirezorbuojantiems chirurginiams siūlams, atsižvelgiant į jo taikymo vietą. Atramat® Nailono (poliamido) chirurginių siūlų naudojimas priklausys nuo bendros paciento būklės, chirurgo patirties, chirurgijos technikos ir uždaromos žaizdos.

Pirmas leidimas: 2015-11-29

Data: 2020-10-23

Galioja iki: 2024-05-26

EB Sertifikatas - visiško kokybės užtikrinimo sertifikavimo patvirtinimas

papildoma sertifikato informacija CE 633494

Nr. **CE633494**
 Išduota: **International Farmaceutica, S.A. de C.V.**
Carreteraco Nr. 44
Caolonia Parque San Andres
Coyoacan
C.P. 04040
Ciudad de Meksika
Meksika

IIb klasė		
GMDN kodas	Produkto pavadinimas	Paskirtis pagal naudojimosi instrukciją
---	Atramat® šilkiniai chirurginiai siūlai	Atramat® šilkiniai chirurginiai siūlai yra skirti naudoti gydant ir (arba) apskritai perrišant minkštuosius audinius, taip pat oftalmologinėms procedūroms. Jie turi būti naudojami pagal priimtinas chirurgines procedūras ir metodus, naudojamus nesirezorbuojantiems siūlams, atsižvelgiant į jo taikymo vietą. Atramat® šilkiniai chirurginių siūlų naudojimas priklausys nuo bendros paciento būklės, chirurgo patirties, chirurgijos technikos ir uždaromos žaizdos.
---	Atramat® Kaulų vaškas	Atramat® Kaulų vaškas yra naudojamas kaulų paviršių kraujavimui kontroliuoti, veikiant fizinį kaulų kanalų tamponavimą. Atidarius, jis turi būti suminkštintas taikant aseptikos metodą, kol bus pasiekta pageidaujama konsistencija, kuri bus taikoma ant kaulo paviršiaus, jei to reikės chirurginėje procedūroje arba jei chirurgas pageidauja.

Pirmas leidimas: 2015-11-29

Data: 2020-10-23

Galioja iki: 2024-05-26

bsi.



By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 566541
Issued To: Davol, Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Boulevard
Warwick
Rhode Island
02886
USA

In respect of:

The design, development and manufacture of fully absorbable, partially absorbable, and non-absorbable synthetic meshes and porcine collagen meshes for soft tissue repair and reconstruction, with or without mesh positioning system; absorbable and non-absorbable fixation devices for mesh fixation and soft tissue approximation; bovine collagen haemostasis devices and associated delivery system; absorbable polysaccharide based clotting beads and associated manual applicators for interoperative surgical applications. Those aspects of Annex II related to securing and maintaining sterility in the manufacture of inflation assembly sets.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2010-11-05**

Date: **2021-02-05**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284

BSI logo

EB Sertifikatas – Pilna kokybės užtikrinimo sistema

Medicinos Prietaisų Direktyva 93/42/EEC, Priedas II, išskyrus skyrių 4.

Nr. CE 566541
Išduotas:
Davol, Inc.
C.R. Bard, Inc. filialui
100 Crossings Boulevard
Warwick
Rhode Island
02886
JAV

Dėl:

Pilnai besirezorbuojančių, dalinai besirezorbuojančių, nesirezorbuojančių sintetinių tinklelių ir kiaulių kolageno tinklelių, skirtų minkštųjų audinių atstatymui ir rekonstrukcijai, su ar be tinklo pozicionavimo sistemos; besirezorbuojančių ir nesirezorbuojančių tinklelio fiksavimo ir minkštųjų audinių sutvirtinimo priemonių; kraujavimą stabdančių priemonių iš jaučio kolageno ir su jomis susijusių pritaikymo priemonių; besirezorbuojančių polisacharido pagrindu pagamintų krešėjimo dalelių ir su jomis susijusių rankiniu būdu valdomų aplikatorių chirurginėms procedūroms ir vietiniam pirmosios pagalbos ir pooperaciniam naudojimui; kūrimo, vystymo ir gamybos.

remiantis mūsų patikrinimu, atliktu pagal Tarybos Direktyvą 93/42/EEC, Priedą II, išskyrus skyrių 4.

Kokybės užtikrinimo sistema atitinka Direktyvos reikalavimus. III klasės produktų pardavimui reikalingas Priedo II, skyriaus 4 sertifikatas.

BSI, kaip Notifikuotos aukščiau paminėtos direktyvos (Notifikuotos Įstaigos Numeris 2797 įstaigos vardu:

Parašas

Gary E Slack, Vyresnysis Vice Prezidentas, Medicinos Prietaisai

Pirmas išdavimas: 2010 m. lapkričio 5d.

Data: 2021 m. vasario 5 d.

Galioja iki: 2024 m. gegužės 26 d.

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Šio sertifikato galiojimas yra ribojamas kokybės sistemos, kuri taikoma pagal Direktyvos reikalavimus ir yra atidžiai prižiūrimas Notifikuotos įstaigos. Šis patvirtinimas neapima visų priekių, kurios sukurtos ir/ar pagamintos trečiųjų šalių įmonės, kuriai išduotas sertifikatas, vardu, nebent specialiai susitarta su BSI. Šis sertifikatas buvo išduotas elektroniniu būdu ir jam taikomos sutarties sąlygos.

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC DESIGN-EXAMINATION CERTIFICATE

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 190023

The Electrotechnical Testing Institute, Notified Body No. 1014, performed the design examination of medical device

**Polydox monofilament, C-TEC Cynadox monofilament
Sterile synthetic absorbable surgical suture with or without atraumatic needle, class III**

in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices
(Annex II clause 4 of Directive 93/42/EEC) at

manufacturer **CHIRANA T. Injecta, s.r.o.**
Komořanská 2148, 143 00 Praha 4 - Modřany, Czech Republic

and states that the design of medical device meets the provisions of Government Order No. 54/2015 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. MED000018-08/01 of: 05.08.2019.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex 1 of Government Order No. 54/2015 Coll. (Annex I of Directive 93/42/EEC). In that case the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 1

The first issue of this certificate from 13.08.2019 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague


Mgr. Miroslav Sedláček
Head of Certification Body



MED000018-08

EB PROJEKTO-PATIKRINIMO SERTIFIKATAS

išduotas pagal Vyriausybės įsakymo Nr. 54/2015 2 priedą Nr. (Direktyvos 93/42/EEB II priedas)

Nr. MED 190023

Elektrotechnikos bandymų institutas, notifikuotoji įstaiga Nr. 1014, atliko medicinos prietaiso projekto patikrinimą

Polydox monofilament, C-TEC Cynadox monofilament
Sterilus sintetinis besirezorbuojantis chirurginis siūlas su arba be atraumatinės adatos, klasė III

vadovaujantis vyriausybės įsakymo Nr. 54/2015 Rink., kuriame nurodyti techniniai reikalavimai medicinos prietaisams (Direktyvos 93/42/EEB II priedo 4 punktas)

gamintojas **CHIRANA T. Injecta, s.r.o.**
Komočanska 2148, 143 00 Praha 4 - Modrany, Čekijos Respublika

ir teigia, kad medicinos prietaiso dizainas atitinka Vyriausybės įsakymo Nr. 54/2015 Rink. (Direktyva 93/42/EEB).

Ši medicinos prietaiso projekto ekspertizės informacija pateikta 2019 m. Rugpjūčio 5 d. Audito ataskaitoje Nr. MED000018-08/01.

Gamintojas privalo pranešti notifikuotajai įstaigai apie ketinimus iš esmės pakeisti patvirtintą medicinos prietaiso projektą, kuris galėtų paveikti esminių reikalavimų atitikimą pagal Vyriausybės nutarimo Nr. 54/2015 Rink. (Direktyvos 93/42/EEB I priedas). Tuo atveju, kai pažeistos sertifikato išdavimo sąlygos, pranešta įstaiga gali patvirtinti sertifikato galiojimą arba anuliuoti sertifikatą.

1 leidimas

Pirmasis šio pažymėjimo išdavimas nuo 2019 m. rugpjūčio 13 d., galiojantis iki 2024 05 26
Šis pažymėjimas galioja iki: 2024 05 26

antspaudas

2019.08.13

parašas

Praha

Mgr. Miroslav Sedlacek
Notifikuotosios įstaigos vadovas

MED000018-08



Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° **EPG-0147-18**
Certificate no.

Addendum n° **//-//**
addendum no.

Data prima emissione **07.11.2018**
First issue date
Data di emissione corrente **07.11.2018**
Current issue date
Data di scadenza **06.11.2023**
Expiry date

ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DESIGN-EXAMINATION CERTIFICATE

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità,
Organismo Notificato 0373, certifica che
il fascicolo di progettazione
del dispositivo medico

The Istituto Superiore di Sanità,
Notified Body 0373, certifies that
the design dossier relating
to the medical device

(vedi allegato tecnico/ see technical sheet)*

fabbricato da

manufactured by

ERGON SUTRAMED S.r.l.

**Sede Legale/ Registered Office:
Via Giuseppe Gregoraci, 12 – 00173 Roma (RM) ITALIA**

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/ Production Site: Zona Industriale – 67062 Magliano dei Marsi (AQ) Italia

è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.



Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **EPG-0147-18**

Addendum n°
addendum no. **//-//**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe: III (Class: III)

Nome prodotto
(Product name)

Darvin Monofilamento - Sutura chirurgica sintetica a lungo assorbimento, monofilamento di poli(L-lattide-co-ε-caprolattone), sterile
(Darvin Monofilamento - Poly(L-lactide-co-ε-caprolactone) monofilament synthetic surgical suture long term absorption, sterile)

Valutazione della Conformità: MOD-341-01-01 n° 267/18
Conformity assessment : MOD-341-01-01 n. 267/18

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2141242DE02

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

GELITA MEDICAL GmbH

**Uferstrasse 7
69412 Eberbach
Germany**

For the product

Sterile non-active implants and wound dressings: GELITA Absorbable Oxidized Cellulose Hemostats: GELITA-CEL®

Documents, that form the basis of this certificate:

**Certification Notice 2141242CN, initially dated 9 February 2011
CE Marking of Conformity 2141242CE02
Addendum, initially dated 16 April 2016**

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 30 November 2022
Issued for the first time: 1 August 2012
Revised: 16 April 2016
Reissued: 27 December 2017

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

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-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2141242DE02

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Sterile non-active implants and wound dressings: GELITA Absorbable Oxidized Cellulose Hemostats: GELITA-CEL®

Issued to:

GELITA MEDICAL GmbH

Uferstrasse 7
69412 Eberbach
Germany

This certificate covers the following product(s):

- GELITA-CEL® STANDARD
- GELITA-CEL® X-Sorb
- GELITA-CEL® Fibrillar

Initial date: 16 April 2016

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

**Mascia Brunelli S.p.A.
Viale Monza 272
20128 Milano
Italy**

for the scope

**CUTANPLAST
(sterile haemostatic absorbable gelatin sponge)**

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

**Annex II – Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid
mdc certificate according to Annex II – excluding section 4 for the
above mentioned products.

Valid from	2018-11-07
Valid until	2023-11-06
Registration no.	D1016000039
Report no.	P18-00656-120573
Stuttgart	2018-10-31



Head of Certification Body



CE Sertifikatas

mdc medical device certification GmbH

Notifikuojantis organas Nr. 0483

patvirtina, kad

Mascia Brunelli S.p.A.

Viale Monza 272

20128 Milan

Italija

šioms sritims

CUTANPLAST

(sterilioms hemostatinėms sugeriamoms želatininėms kempinėms)

EB Dizaino patikros sertifikatas

mdc auditas užtikrina, kad ši kokybės sistema atitinka visus reikalavimus pagal

Tarybos Direktyvos 93/42/EEB, II Priedo 4 skirsnį,

išleistą 1993 06 14 dėl medicinos priemonių.

Šis sertifikatas galioja tik kartu su galiojančiu sertifikatu minėtiems produktams pagal II Priedą, išskyrus 4 skirsnį.

Šis sertifikatas galioja nuo:	2018 11 07
Šis sertifikatas galioja iki:	2023 11 06
Sertifikato reg. Nr.:	D1016000039
Protokolo Nr.	P18-00656-120573
Štutgartas	2018 10 31

(parašas)

Sertifikuojančio organo
direktorius



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 090237 0017 Rev. 00

Manufacturer

NOBAMED Paul Danz AG

Höltkenstr. 1-5
58300 Wetter (Ruhr)
GERMANY

Facility(ies):

NOBAMED Paul Danz AG
Höltkenstr. 1-5, 58300 Wetter (Ruhr), GERMANY

Product Category(ies):

**Swabs, Balls, Wound Dressings, Padding
Dressings and Bandages, Gloves, OR-Clothes,
Drapes, Bandages, Plasters, Umbilical Cord Clamp,
Tongue Depressors, Customized Procedure Trays**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713148089+713155325

Valid from:

2020-02-26

Valid until:

2024-05-26

Date,

2020-02-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE

EC SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEC, Priedas V

(I klasės priemonės yra laikomos steriliose sąlygose ar steriliose pakuotėse)

Nr. G2S 090237 0017 Rev. 00

Gamintojas: NOBAMED Paul Danz AG
Höltken g. 1-5
58300 Wetter (Ruhr)
VOKIETIJA

Adresas: NOBAMED Paul Danz AG
Höltken g. 1-5, 58300 Wetter (Ruhr), VOKIETIJA

Produkto kategorija(os): Tamponai, kamuoliukai, žaizdų tvarščiai, tvarstomoji medžiaga ir tvarščiai, pirštinės, operacinės drabužiai, apklotai, bintai, pleistrai, umbilikaliniai spaustukai, liežuvio prispaudėjai, pagal užsakymą gaminami rinkiniai

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH patvirtina, kad paminėtasis gamintojas įdiegė kokybės užtikrinimo sistemą atitinkamų prietaisų/prietaisų kategorijų gamybai ir galutiniam patikrinimui pagal medicinos prietaisų direktyvos V Priedą. Ši kokybės užtikrinimo sistema apima gamybos aspektus, susijusius su atitinkamų priemonių / priemonių kategorijų sterilumo savybių išlaikymu ir atitinka šios direktyvos sąlygas. Kokybės užtikrinimo sistema turi būti periodiškai peržiūrima. Taip pat žr. kitame lape.

Protokolo Nr. 713148089+713155325

Galioja nuo: 2020-02-26

Galioja iki: 2024-05-26

Data, 2020-02-26

/parašas/
Christoph Dicks
Sertifikavimo/Notifikuotos Įstaigos vadovas

Puslapis 1 iš 1

TÜV SÜD Product Service GmbH yra notifikuota įstaiga, identifikacijos Nr. 0123.



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301011861

Manufacturer: **SMI AG**

Facility: **STEINERBERG 8, 4780 ST. VITH., BELGIUM.**

Products: **1. STERILE NON ABSORBABLE SURGICAL SUTURES.
2. STERILE ABSORBABLE SURGICAL SUTURES.**

Brand names: **As in annex**

Devices Classification: **1. IIb, 2. III**

Current issue date: **01/03/2021**

Valid until: **24/05/2024**

Audit report: **200011861**


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.



ANNEX No. 301011861 CERTIFICATE.

MEDICAL DEVICES	BRAND NAMES
<ul style="list-style-type: none">• <i>Classification IIb</i> <p>1. STERILE NON ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• POLYPROPYLENE• POLYESTER• SILK• NYLON DACLON & SUPRAMID
<ul style="list-style-type: none">• <i>Classification III</i> <p>2. STERILE ABSORBABLE SURGICAL SUTURES.</p>	<ul style="list-style-type: none">• SURGICRYL PGA• SURGICRYL MONOFILAMENT• SURGICRYL RAPID• SURGICRYL 910• SURGICRYL MONOFAST

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.

EC Certificate Full Quality Assurance System: Certificate US19/819943647.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 06866

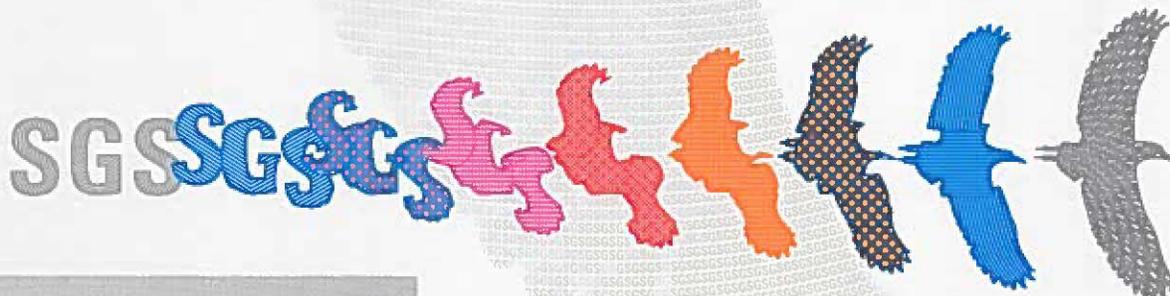
Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev 02

Page 1 of 3



Teleflex Medical

Directive 93/42/EEC

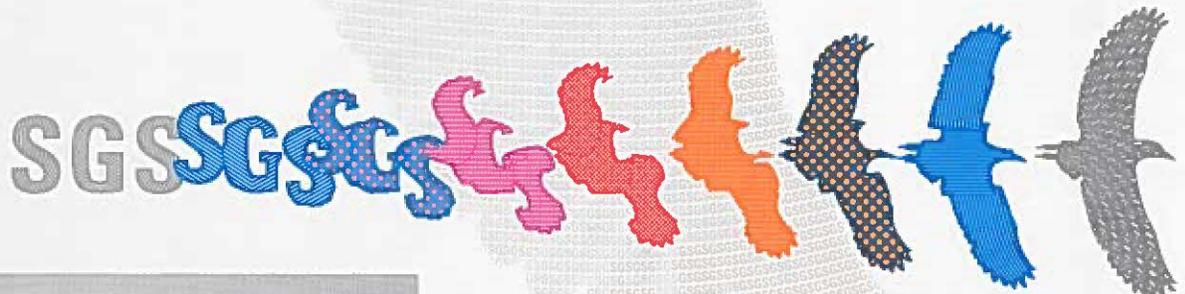
on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

- Sterile Hem-o-lok and Vesolock Ligation Clips,**
- Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesoclude**
- Metal Ligation Clips Sterile Deknatel® PTFE pledgets.**
- Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II,**
- "silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®).**
- Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM**
- and polypropylene non-absorbable surgical sutures.**
- Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical**
- Sutures. Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.**
- Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.**
- Sterile Hem-o-lok Automatic Clip Appliers.**
- Metal Ligation System.**

- Sterile and Non-sterile External stapling system (including stainless steel staples,**
- staplers and removers), Sterile, Efx endo fascial closure system (abdominal access),**
- Sterile, Efx shield fascial closure system (abdominal access),**
- Sterile, Efx classic fascial closure system (abdominal access)**
- Sterile stainless steel surgical Sutures**
- Sterile FORCE FIBER® surgical sutures.**
- Sterile Chest drainage and autotransfusion systems, Sterile Thoracic Catheters,**
- Sterile and Non-sterile Aortic Punch,**
- Non-sterile Self Retaining Tissue retractor/blades**



Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

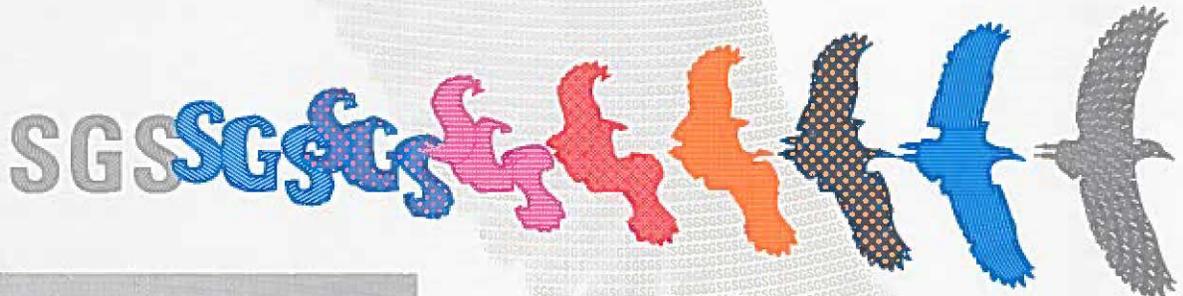
Detailed scope

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non-sterile Respiratory and anaesthesia masks, Non-sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States



EB sertifikato visiško kokybės užtikrinimo sistema: sertifikatas US19/81994367.00

Valdymo sistema

Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, JAV

buvo įvertinta ir sertifikuota kaip atitinkanti

Direktyvos 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsnį) reikalavimus

Šiems produktams

Registracijos sritis pateikiama šio sertifikato 2 puslapyje.
Šis sertifikatas galioja nuo 2020 m. Vasario 24 d. iki 2023 m. Liepos 14 d.
Ir lieka galiojantis atlikus patikimos priežiūros auditą.
2 leidimas. Sertifikuota nuo 2000 m. Rugsėjo 26 d.
ir pirmą kartą sertifikuota „SGS Belgium NV“ nuo 2020 m. vasario 1 d.

Šiai sričiai buvo išduoti keli sertifikatai.
Pagrindinis sertifikatas numeruojamas US19/819943647.00

Šis sertifikatą sudaro keli puslapiai
Papildoma informacija pateikiama tolesniuose puslapiuose

Sertifikavimas pagrįstas ataskaitomis, kurių numeris WW/MC 06866

Įgaliojo

parašas

SGS Belgium NV, notifikuotoji įstaiga 1639

SGS House Noorderlaan 87 2030 Antverpenas, Belgija
t el. + 32 (0) 545-48-48 fax. +32 (0) 545-48-49 www.sgs.com

LPMD5007 sertifikatas CE1639 II-4_LT priedas. 02

1 puslapis iš 3

Teleflex Medical

Direktyva 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsnį) reikalavimus

2 leidimas

Išsami taikymo sritis

**Sterilios Hem-o-lok ir Vesolock ligatūrinės kabutės
Sterilios ir nesterilios Hemoclip Traditional, Hemoclip Plus, Horizon ir
Vesoclude
metalinės kabutės. Sterilūs Deknatel PTFE lopeliai.
Sterilūs nesirezorbuojantys poliesterio siūlai (POLYLENE/ „cotony“ II,
„silky“ II POLYDEK, TEVDEK, NextStich, Capiro, NiceLoop, TEVDEK)
Sterilūs DEKLENE II, DEKLENE MAXXTM, CAPIOTM
ir polipropileno nesirezorbuojantys chirurginiai siūlai.
Sterilūs BONDEK ir BONDEK Plus poliglikolinės rūgšties besirezorbuojantys
chirurginiai siūlai. Sterilūs Polyglytone 6211 monofilamentiniai
besirezorbuojantys chirurginiai siūlai.
Sterilūs MONODEK polydioksanono besirezorbuojantys chirurginiai siūlai.
Sterilūs Hem-o-lok automatinis kabučių aplikatorius.
Metalinė ligavimo sistema.**

**Sterili ir nesterili išorinė odos susegimo sistema (įskaitant ir nerūdijančio plieno
staplerius ir kabučių išėmėjus), Sterili EFx endo fascinio uždarymo sistema
(pilvo prieiga),
Sterili EFx viršutinė fascinio uždarymo sistema (pilvo prieiga),
Sterili EFx klasikinė fascinio uždarymo sistema (pilvo prieiga),
Sterilūs plieniniai chirurginiai siūlai
Sterilūs FORCE FIBER chirurginiai siūlai
Sterilios krūtinės drenažo ir autotransfūzinės sistemos, sterilūs troakaro
kateteriai
Sterilūs ir nesterilūs aortos skylamušiai
Nesterilus savaime išsilaikantis audinių retractorius, mentės**

Teleflex Medical

Direktyva 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsni) reikalavimus

2 leidimas

Išsami taikymo sritis

Nesterilios anestezijos ir kvėpavimo sistemos, įskaitant kvėpavimo maišelius ir vandens gaudyklės, nesterilūs šildomi drėkintuvai, nesterilūs, neužpildyti Drėkintuvai ir purkštuvai, nesterilūs nedidelio tūrio purkštuvai, Sterilūs užpildyti drėkintuvai ir purkštuvai (fiziologinis tirpalas arba vanduo) su adapteriais, Sterilus užpildytas vienkartinis dozatorius/tirpalas purškimui, Nesterilūs kvėpavimo terapijos adapteriai ir jungtys, Sterili kolona ir rezervuarai, įskaitant adapterius, nesterili nosies kaniulė (Įskaitant dujų mėginių ėmimą), nesterili kaniulė ir maitinimo vamzdeliai, nesterilus CPAP Kaniulių sistema, nesterilūs rankiniai gaivinimo aparatai ir PEEP vožtuvai, Nesterilios kvėpavimo ir anestezijos kaukės, Nesterili dujų šalinimo kaukė, sterilūs endotrachėjos vamzdeliai, Sterilūs Endobronchiniai vamzdeliai, nesterilūs siurbimo ir aspiravimo vamzdeliai, Sterilūs ventiliuojami krūtinės ląstos krūtinės įspaudai, sterilūs operaciniai cholangiogramos kateteriai, Sterilūs pilvo prieigos ir susiurbimo prietaisai, Sterili kapiliarų drenažo sistema, sterili perkutaninė chirurginė sistema (MiniLap ir rankenos griebtuvai), sterili perkutaninė chirurginė sistema („Mini Polar“ zondas ir MiniGrip Bipolar Graspers), Nesterilūs šilumos ir drėgmės keitikliai

Jei pirmiau minėta taikymo sritis apima III klasės medicinos prietaisą (-us), galiojantis EB projekto tyrimo sertifikatas pagal II priedą (4 skirsni) yra privalomas kiekvieno prietaiso reikalavimas, be šio sertifikato, norint pateikti tą prietaisą į rinką.

375 Forbes Blvd, Mansfield, MA, 02048-1805, USA

Dokumentas elektroniniu
parašu pasirašė DOVILĖ
ANDRIJAUSKAITĖ
Data: 2021-08-23 13:20:38
Paskaitis Pirkimo Nr.
556674
Vieta: Energetikų g. 8, LT-
52461, Kaunas
Kontaktinė informacija:
Viešųjų pirkimų specialistė