EC Certificate Production Quality Assurance System: Certificate ES13/88103

The management system of

BASTOS VIEGAS, SA

Avenida da Fábrica, 298,
4560-164 Guilhufe–Penafiel. Portugal

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

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

This certificate is valid from 08 August 2019 until 31 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 June 2021
Issue 13. Certified since 21 February 2013

Certification is based on reports numbered ES/MAD 228876

Authorised by

Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 18 0811 M2

BASTOS VIEGAS, SA

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Issue 13

Detailed scope

Sterile, single use non-invasive non-woven dressings.
Sterile, single use orthopedic padding, elastic and tubular bandages.
Sterile, single use non-adherent wound dressings.
Sterile, single use absorbent pads, maternity pads and first aid dressings.
Sterile, single use non-invasive, gauze dressings, eye pads.
Sterile, single use non-invasive forceps, and umbilical cord clamps.
Sterile, single use tongue depressor.
Sterile, single use Ayre spatula.
Sterile, single use, eye shield.
Sterile, single use surgical drapes and draping sets.
Sterile, single use operating room towels, towel clamps, incise drapes, instrument pouches, fluid pouches, tube holders, adhesive tape for operations and surgical absorbent pads.
Sterile, single use protection blankets for patients in emergencies and baby blankets.
Sterile, single use disinfectant applicators.
Sterile, single use procedure sets.
Sterile single use plastic skin staple remover.
Sterile single use guidewire bowls for preparation and temporary storage of guidewire while keeping it in place and hydrated.

Material de penso de não-tecido, não-invasivo, estéril e de uso único.
Ligaduras ortopédicas, elásticas e tubulares, estéreis e de uso único.
Material de penso não-aderente estéril e de uso único.
Pensos absorventes, pensos de maternidade e compressas de primeiros socorros estéreis e de uso único.
Material de penso de gaze não-invasivo, pensos oftálmicos estéreis e de uso único.
Pinças não-invasivas e clamp umbilical, estéreis e de uso único.
Abaixa-línguas estéril e de uso único.
Espátula d'Ayre estéreis e de uso único.
Protector ocular estéril e de uso único.
Campos cirúrgicos e sets de cobertura, estéreis e de uso único.
Toalha de bloco operatório, clamp de campos, campos de incisão, bolsas de instrumentos, bolsas de recolha de fluídos, segura-tubos, adesivo para operações e almofada absorvente cirúrgica, estéreis e de uso único.
Lençol de protecção para pacientes em situação de emergência e lençol de bebé, estéreis e de uso único.
Aplicadores para desinfecção estéreis e de uso único.
Sets de procedimento, estéreis e de uso único.
Removedor de agrafos plástico, estéril e de uso único.
Recipiente fio-guia estéril e de uso único, destinado à preparação e armazenamento temporário do fio-guia, mantendo-o na sua posição e hidratado.

CE Sertifikatas Gamybos Kokybės Užtikrinimo Sistema: Sertifikatas ES13/88103

Valdymo sistema

BASTOS VIEGAS, SA

Avenida da Fabrica, 298,
4560-164 Guilhufe-Penafiel. Portugalija

Buvo patvirtinta ir sertifikuota kaip atitinkanti

Direktyva 93/42/EEC

apimanti medicinos prietaisus, Priedas V
Apibrėžianti gamybos aspektus, kaip užtikrinti ir palaikyti sterilias sąlygas.

reikalavimus šiems produktams

Registracijos taikymo sritis yra šio sertifikato 2 lape.

Sertifikatas galioja nuo 2019 rugpjūčio 8 dienos iki 2023 liepos 31 dienos
ir lieka galioti tinkamai audituojant
Resertifikacijos audito data: prieš 2021 Birželio 22 diena
Išdavimas 13. Sertifikuota nuo 2013 vasario 21 dienos

Sertifikatas paremtas ES/MAD 28876 ataskaitomis

Pasirašytas

/parašas/

SGS United Kingdom Ltd, Notifikuota įstaiga 0120
/rekvizitai/

SGS CE 18 0811 M2

BASTOS VIEGAS, SA

Direktyva 93/42/EEC

apimanti medicinos prietaisus, Priedas V
Apibrėžianti gamybos aspektus, kaip užtikrinti ir palaikyti sterilias sąlygas.

13 išdavimas

Detali sritis

Sterilūs, vienkartiniai neinvaziniai neaustiniai tvarsčiai.
Sterilūs, vienkartiniai ortopediniai, elastiniai ir tubuliariniai tvarsčiai.
Sterilūs, vienkartiniai nelipnūs žaizdų tvarsčiai.
Sterilūs, vienkartiniai absorbuojantys, motinystės, pirmosios pagalbos tvarsčiai.
Sterilūs, vienkartiniai neinvaziniai marliniai tvarsčiai, akių tvarsčiai.
Sterilios, vienkartinės neinvazinės žnyplės ir virkštelės spaustukai.
Sterilūs, vienkartiniai liežuvio špadeliai.
Sterili vienkartine Ayre mentelė.
Sterili, vienkartinė akies apsauga.
Sterilūs, vienkartiniai chirurginiai apklotai ir apklotų rinkiniai.
Sterilūs, vienkartiniai operacinės rankšluosčiai, jų laikikliai, incizinė plėvelė, instrumentų maišeliai, skysčių maišeliai, vamzdelių laikikliai, lipni juosta operacijos ir sugeriamieji paklotai.
Sterilūs, vienkartiniai dezinfekcijos aplikatoriai.
Sterilūs, vienkartiniai procedūrų rinkiniai.
Sterilūs, vienkartiniai odos siuvimo aparato kabučių išėmikliai.
Sterilūs, vienkatiniai pravedimo vielos dubenėliai paruošimui ir laikinam pravedimo vielos laikymui išlaikant ją sudrėkintą.

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2022-MDR/QS-027

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia
SRN No.: SK-MF-000003702

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Non-active and Non-implantable Medical Devices:
Tubular Devices
Adapters, Connectors, Ramps, Stopcock, Caps
Arterio-Venous System Devices
(For detailed list refer to Annex I)

Intended purpose: See Annex II
MD class IIa

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR077_2022 from 21.09.2022, MD Clinical Evaluation Report No. MDR077_2022 from 21.09.2022 and MD Audit Report No. SK-0655/22 from 21.09.2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **30.09.2022**
Valid until: **30.09.2027**
First issue: **30.09.2022**
Revision: **00**
History: **Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 30.09.2022

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Tubular Devices

Product	Trade Name	Models	REF code
Infusion Set for Single Use	CHIRAPLUS G	CHIRAPLUS G	CHG301
		CHIRAPLUS G	CHG317
		CHIRAPLUS G	CHG318
		CHIRAPLUS G	CHG331
		CHIRAPLUS G with needle	CHG319
		CHIRAPLUS G with metal spike	CHG316
		CHIRAPLUS G DEHP free	CHG501
		CHIRAPLUS G DEHP free	CHG518
		CHIRAPLUS G DEHP free	CHG531
		CHIRAPLUS G DEHP free	CHG901
		CHIRAPLUS G DEHP free, PVC free	CHG731
Infusion Set for Single Use	CHIRAPLUS P	CHIRAPLUS P	CHP306
		CHIRAPLUS P	CHP318
		CHIRAPLUS P	CHP336
		CHIRAPLUS P	CHP339_170
		CHIRAPLUS P	CHP339_185
		CHIRAPLUS P	CHP339_190
		CHIRAPLUS P DEHP free	CHP506
		CHIRAPLUS P DEHP free	CHP536
		CHIRAPLUS P DEHP free	CHP538
		CHIRAPLUS P DEHP free	CHP576
		CHIRAPLUS P SAFETY	CHP338
		CHIRAPLUS P SAFETY	CHP337

Versions:

- with solution filter
- with or without air ventil
- with or without flow regulator
- with or without needle
- drip chamber transparent or colour photo-sensitive
- Luer / Luer-Lock with cap
- with or without flashball
- with or without check valve
- with auto air stop and priming filter
- micro drip / burette
- with or without DEHP

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Tubular Devices

Product	Trade Name	Models	REF code
Transfusion Set for Single Use	**CHIRAHEM**	CHIRAHEM	CHT314
		CHIRAHEM	CHT315
		CHIRAHEM	CHT320
		CHIRAHEM	CHT323
		CHIRAHEM with needle	CHT321
		CHIRAHEM with metal spike	CHT322
		CHIRAHEM DEHP Free	CHT514
		CHIRAHEM DEHP Free	CHT515
		CHIRAHEM DEHP Free	CHT516
		CHIRAHEM DEHP Free	CHT517
		CHIRAHEM DEHP Free	CHT518

Versions:
- with blood filter
- with and without air ventil
- with or without flow regulator
- with or without needle
- Luer / Luer-Lock with cap
- with or without flashball
- with or without DEHP

Tubular Devices

Product	Trade Name	Models	REF code
Extension Line for Single Use	**CHIRALINE**	450mm	CHL318045
		1800mm	CHL318180

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM
CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Adapters, Connectors, Ramps, Stopcock, Caps

Product	Trade Name	Models	REF code
Mandrin for Single Use	CHIRAFLEX	14G	CHFX20014
		16G	CHFX20016
		17G	CHFX20017
		18G	CHFX20018
		20G	CHFX20020
		22G	CHFX20022
		24G	CHFX20024
		26G	CHFX20026

Adapters, Connectors, Ramps, Stopcock, Caps

Product	Trade Name	Models	REF code
Three Way Stop Cock for Single Use	CHIRAWAY	Standard	CHW001
		Lipid resistant	CHW002

Adapters, Connectors, Ramps, Stopcock, Caps

Product	Trade Name	Models	REF code
Stopper for Single Use	CHIRAPLUS	Stopper Luer-Lock	CHLL01
		Combistopper red	CHCS01
		Combistopper blue	CHCS02
		Combistopper white	CHCS03

Adapters, Connectors, Ramps, Stopcock, Caps

Product	Trade Name	Models	REF code
Port for Single Use	CHIRAPLUS	Needle free injection port	CHINF01
		Injection port	CHIP01

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	14G with port, snap fit cap & suturable wings	CHFX0101445
		14G with port, snap fit cap & suturable wings	CHFX0101450
		16G with port, snap fit cap & suturable wings	CHFX0101645
		17G with port, snap fit cap & suturable wings	CHFX0101745
		18G with port, snap fit cap & suturable wings	CHFX0101832
		18G with port, snap fit cap & suturable wings	CHFX0101840
		18G with port, snap fit cap & suturable wings	CHFX0101845
		20G with port, snap fit cap & suturable wings	CHFX0102030
		20G with port, snap fit cap & suturable wings	CHFX0102032
		20G with port, snap fit cap & suturable wings	CHFX0102033
		22G with port, snap fit cap & suturable wings	CHFX0102225
		24G with port, snap fit cap & suturable wings	CHFX0102419
		26G with port, snap fit cap & suturable wings	CHFX0102619
		14G without port & with wings (without injection port)	CHFX0201445
		16G without port & with wings (without injection port)	CHFX0201645
		17G without port & with wings (without injection port)	CHFX0201745
		18G without port & with wings (without injection port)	CHFX0201845
		20G without port & with wings (without injection port)	CHFX0202032
		20G without port & with wings (without injection port)	CHFX0202033
		22G without port & with wings (without injection port)	CHFX0202225
		24G without port & with wings (without injection port)	CHFX0202419
		26G without port & with wings (without injection port)	CHFX0202619
		14G without injection port & without wings	CHFX0301445
		16G without injection port & without wings	CHFX0301645
		17G without injection port & without wings	CHFX0301745

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

3EC®
international

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	18G without injection port & without wings	CHFX0301832
		18G without injection port & without wings	CHFX0301845
		20G without injection port & without wings	CHFX0302032
		22G without injection port & without wings	CHFX0302225
		24G without injection port & without wings	CHFX0302419
		26G without injection port & without wings	CHFX0302619
		14G safety - with port, snap fit cap & suturable wings	CHFXS0101445
		16G safety - with port, snap fit cap & suturable wings	CHFXS0101645
		17G safety - with port, snap fit cap & suturable wings	CHFXS0101745
		18G safety - with port, snap fit cap & suturable wings	CHFXS0101832
		18G safety - with port, snap fit cap & suturable wings	CHFXS0101845
		20G safety - with port, snap fit cap & suturable wings	CHFXS0102032
		20G safety - with port, snap fit cap & suturable wings	CHFXS0102033
		22G safety - with port, snap fit cap & suturable wings	CHFXS0102225
		24G safety - with port, snap fit cap & suturable wings	CHFXS0102419
		26G safety - with port, snap fit cap & suturable wings	CHFXS0102619
		14G safety - without port & with wings (without injection port)	CHFXS0201445
		16G safety - without port & with wings (without injection port)	CHFXS0201645
		17G safety - without port & with wings (without injection port)	CHFXS0201745
		18G safety - without port & with wings (without injection port)	CHFXS0201832
		18G safety - without port & with wings (without injection port)	CHFXS0201845
		20G safety - without port & with wings (without injection port)	CHFXS0202032
		22G safety - without port & with wings (without injection port)	CHFXS0202225
		24G safety - without port & with wings (without injection port)	CHFXS0202419
		26G safety - without port & with wings (without injection port)	CHFXS0202619

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	14G safety - without injection port & without wings	CHFXS0301445
		16G safety - without injection port & without wings	CHFXS0301645
		17G safety - without injection port & without wings	CHFXS0301745
		18G safety - without injection port & without wings	CHFXS0301832
		18G safety - without injection port & without wings	CHFXS0301845
		20G safety - without injection port & without wings	CHFXS0302032
		22G safety - without injection port & without wings	CHFXS0302225
		24G safety - without injection port & without wings	CHFXS0302419
		26G safety - without injection port & without wings	CHFXS0302619

Versions:
- with port, snap fit cap & suturable wings
- without injection port & with wings
- without injection port & without wings
- safety versions

Sizes: 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Infusion Set for Single Use: CHIRAPLUS G / CHIRAPLUS P - administration liquids and drugs into the circulation system by using of intravenous catheters and cannulas

Transfusion Set for Single Use: CHIRAHEM - administration blood into the circulation system by using of intravenous catheters and cannulas

Extension Line for Single Use: CHIRALINE - connection and extension infusion or transfusion sets for administration liquids or blood into the circulation system by using of intravenous catheter and cannula

Mandrin for Single Use: CHIRAFLEX - long term closure of the intravascular catheters

Three Way Stop Cock for Single Use: CHIRAWAY - administration of fluids and drugs into the human circulating system – to provide access into the peripheral vascular systems through I.V. Cannula for administration of two fluids or drugs at the same time

Stopper for Single Use: CHIRAPLUS - closure of Luer Lock connectors

Port for Single Use: CHIRAPLUS - connection of medical devices, additional input into the system by the drug administration

I.V. Cannula for Single Use: CHIRAFLEX / CHIRAFLEX SAFETY - access into the peripheral vascular system for administration of fluids and drugs and for withdrawal of blood at patient

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-027	30.09.2022	MDR105_2022, MDR106_2022, MDR107_2022, MDR108_2022, MDR110_2022, MDR111_2022, MDR114_2022, MDR115_2022	Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR.

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073403 0025 Rev. 03

Manufacturer:

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Infusion Pump, I.V. Cannula, Reinforced Endotracheal Tube, Laryngeal Mask Airway, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit, Nasal Oxygen Tube, Heat and Moisture Exchanger, Suction Handle, Manual Resuscitator, LOR Indicator Syringe, Disposable Pressure Transducer.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1973704

Valid from: 2019-11-21
Valid until: 2024-05-26

Date, 2019-11-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073403 0025 Rev. 03

Facility(ies):

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400
Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Middle of Weft 7 Road, Nanpu District, 453400 Changyuan
County, Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema
Medicinos prietaisų direktyva 93/42/EEC (MDD), II priedas, išskyrus (4)
(Įrenginiai klasėje IIa, IIb arba III)
Nr. G1 073403 0025 Rev. 03

Gamintojas: Henan Tuoren Medical Devices Co., Ltd.
Weiyuan industrnė zona
Menggang, Changyuan County
453400 Henan,
Kinijos Liaudies Respublika

Produkto kategorijos: Endotrachėjniai vamzdeliai, Tracheostominiai vamzdeliai, Endobronchiniai vamzdeliai, Infuzinės pompos, I.V. Kaniulės, Sustiprinti endrotrechėjiniai vamzdeliai, Gerklų kaukė kvėpavimo takams, Foley kateterių rinkiniai, Atsiurbimo kateteriai, Kvėpavimo kontūras, Deguonies kaukė, Anestezinė kaukė, Guedel Airway, Endotrachėjinis intubacinis rinkinys, Nosies deguonies vamzdelis, Šilumos ir drėgmės keitiklis, Atsiurbimo rankenėlė, Rankinis gaivinimo aparatas, LOR indikatoriaus švirkštas, Vienkartinis slėgio keitiklis.

Pranešimo numeris: BJ1973704

Galioja nuo: 2019-11-21
Galioja iki: 2024-05-26

Data, 2019-11-21

Parašas//
Christoph Dicks
Sertifikavimo / Notifikuotosios įstaigos vadovas

CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema
Medicinos prietaisų direktyva 93/42/EEC (MDD), II priedas, išskyrus (4)
(Įrenginiai klasėje IIa, IIb arba III)
Nr. G1 073403 0025 Rev. 03

Paslaugos: Henan Tuoren Medical Devices Co., Ltd.

Weiyuan Industinė zona, Menggang, Changyuan County, 453400

Henan, Kinijos Liaudies Respublika

Henan Tuoren Medical Devices Co., Ltd.

Middle of Weft 7 Road, Nanou District, 453400 Changyuan

County, Henan, Kinijos Liaudies Respublika

Henan Tuoren Medical Devices Co., Ltd.

Mancun Industrinė Zona, Changyuan County, 453400, Henan,

Kinijos Liaudies Respublika

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2021.106.14392-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Klas Medikal Cihazlar Sanayi Mümessillik İç ve Dış Tic. Ltd. Şti.
Company Address	: Ramazanoğlu Mah. Mahsus Sk. Klas Medikal Blok No:1 İç Kapı No:1 Pendik İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Antimicrobial Drape - Class III, Sterile
Product Brand/Model/Type	: HITEC
GMDN	: 47783

This certificate has been issued based on Ministry of Health's E-61749811-511.14-378880 numbered scientific opinion taken on 23.03.2021 according to 93/42/EEC Annex I Art .7.4

Product Types are attached.

Certificate Number	: M.2021.106.14392
Report Number	: MD.3466.IB
Initial Assessment Date	: 10.10.2019
Registration Date	: 26.03.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14392 and with the registration date of 26.03.2021 issued for "Klas Medikal Cihazlar Sanayi Mümessillik İç ve Dış Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Ref. No	Description	GMDN	Ref. No	Description	GMDN
ID0510	Antimicrobial Drape 5x10 cm	47783	ID4530	Antimicrobial Drape 45x30 cm	47783
ID0607	Antimicrobial Drape 6x7 cm	47783	ID4535	Antimicrobial Drape 45x35 cm	47783
ID1012	Antimicrobial Drape 10x12 cm	47783	ID4540	Antimicrobial Drape 45x40 cm	47783
ID1020	Antimicrobial Drape 10x20 cm	47783	ID4545	Antimicrobial Drape 45x45 cm	47783
ID1030	Antimicrobial Drape 10x30 cm	47783	ID4548	Antimicrobial Drape 45x48 cm	47783
ID1050	Antimicrobial Drape 10x50 cm	47783	ID4555	Antimicrobial Drape 45x55 cm	47783
ID1060	Antimicrobial Drape 10x60 cm	47783	ID4560	Antimicrobial Drape 45x60 cm	47783
ID1520	Antimicrobial Drape 15x20 cm	47783	ID4565	Antimicrobial Drape 45x65 cm	47783
ID1528	Antimicrobial Drape 15x28 cm	47783	ID4590	Antimicrobial Drape 45x90 cm	47783
ID1530	Antimicrobial Drape 15x30 cm	47783	ID5045	Antimicrobial Drape 50x45 cm	47783
ID1620	Antimicrobial Drape 16x20 cm	47783	ID5060	Antimicrobial Drape 50x60 cm	47783
ID2010	Antimicrobial Drape 20x10 cm	47783	ID5580	Antimicrobial Drape 55x80 cm	47783
ID2020	Antimicrobial Drape 20x20 cm	47783	ID5640	Antimicrobial Drape 56x40 cm	47783
ID2030	Antimicrobial Drape 20x30 cm	47783	ID5645	Antimicrobial Drape 56x45 cm	47783
ID2040	Antimicrobial Drape 20x40 cm	47783	ID5660	Antimicrobial Drape 56x60 cm	47783
ID2525	Antimicrobial Drape 25x25 cm	47783	ID5680	Antimicrobial Drape 56x80 cm	47783
ID2815	Antimicrobial Drape 28x15 cm	47783	ID5685	Antimicrobial Drape 56x85 cm	47783
ID2830	Antimicrobial Drape 28x30 cm	47783	ID5690	Antimicrobial Drape 56x90 cm	47783
ID2840	Antimicrobial Drape 28x40 cm	47783	ID5766	Antimicrobial Drape 57x66 cm	47783
ID2845	Antimicrobial Drape 28x45 cm	47783	ID6030	Antimicrobial Drape 60x30 cm	47783
ID3020	Antimicrobial Drape 30x20 cm	47783	ID6035	Antimicrobial Drape 60x35 cm	47783
ID3027	Antimicrobial Drape 30x27 cm	47783	ID6040	Antimicrobial Drape 60x40 cm	47783
ID3030	Antimicrobial Drape 30x30 cm	47783	ID6045	Antimicrobial Drape 60x45 cm	47783
ID3035	Antimicrobial Drape 30x35 cm	47783	ID6050	Antimicrobial Drape 60x50 cm	47783
ID3040	Antimicrobial Drape 30x40 cm	47783	ID6055	Antimicrobial Drape 60x55 cm	47783
ID3045	Antimicrobial Drape 30x45 cm	47783	ID6060	Antimicrobial Drape 60x60 cm	47783
ID3050	Antimicrobial Drape 30x50 cm	47783	ID6070	Antimicrobial Drape 60x70 cm	47783
ID3060	Antimicrobial Drape 30x60 cm	47783	ID6080	Antimicrobial Drape 60x80 cm	47783
ID3535	Antimicrobial Drape 35x35 cm	47783	ID6085	Antimicrobial Drape 60x85 cm	47783
ID3540	Antimicrobial Drape 35x40 cm	47783	ID6090	Antimicrobial Drape 60x90 cm	47783
ID3545	Antimicrobial Drape 35x45 cm	47783	ID6640	Antimicrobial Drape 66x40 cm	47783
ID3550	Antimicrobial Drape 35x50 cm	47783	ID6645	Antimicrobial Drape 66x45 cm	47783
ID3560	Antimicrobial Drape 35x60 cm	47783	ID6650	Antimicrobial Drape 66x50 cm	47783
ID4030	Antimicrobial Drape 40x30 cm	47783	ID6660	Antimicrobial Drape 66x60 cm	47783
ID4035	Antimicrobial Drape 40x35 cm	47783	ID6685	Antimicrobial Drape 66x85 cm	47783
ID4040	Antimicrobial Drape 40x40 cm	47783	ID6690	Antimicrobial Drape 66x90 cm	47783
ID4042	Antimicrobial Drape 40x42 cm	47783	ID9045	Antimicrobial Drape 90x45 cm	47783
ID4045	Antimicrobial Drape 40x45 cm	47783	ID9050	Antimicrobial Drape 90x50 cm	47783
ID4060	Antimicrobial Drape 40x60 cm	47783	ID9060	Antimicrobial Drape 90x60 cm	47783
ID4528	Antimicrobial Drape 45x28 cm	47783			

UDEM APPROVED 2292

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
T:03124430390 F:03124430376 info@udemltd.com.tr www.udem.com.tr

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

/logotipas/

EC SERTIFIKATAS

Pilna Kokybės Užtikrinimo Sistema

Medicinos Priemonių Direktyva 93/42/EEC Priedas II

(Išskyrus 4 skirsnį)

M.2021.106.14392-1 Dizaino Tyrimo sertifikatas paruoštas III Klasės produktams apibrėžtiems šiame sertifikate

Įmonės pavadinimas	: Klas Medikal Cihazlar Sanayi Mümessillik İç Ve Diş Tic. Ltd. Şti
Įmonės adresas	: Ramazanoğlu Mah. Mahsus Sk. Klas Medikal Blok No:1 Ic Kapi No:1 Pendik / STAMBULAS / TURKIJA
Susijusios Direktyvos ir Priedai	:93/42/EEC Medicinos Priemonių Direktyva – Priedas II (išskyrus 4 skirsnį)
Produktai	: antimikrobinė plėvelė – III klasė, sterilu
Produkto prekinis ženklas	:HITEC
GMDN	:47783

Šis sertifikatas išduotas pagal Sveikatos Ministerijos E-61749811-511 numeruotą mokslinę nuomonių, išreikštą 2021-03-23 pagal 93/42/EEC I Priedo 7.4 str.

Produktų tipai priede

Sertifikato Numeris	:M2021.106.14392	
Ataskaitos Numeris	:MD.3466.IB	/antspaudas/
Pradinio vertinimo data	:2019-10-10	/parašas/
Registracijos data	:2021-03-26	UDEM International Certification
Peržiūros data/Nr.	:-	Auditing Training Centre Industry
Galiojimo data	:2024-05-27	and Trade Inc. Cp.

Šis 1 puslapio dokumentas yra Sertifikato M.2021.106.14392, registruoto 2021-03-26, Išduoto Klas Medikal Cihazlar Sanayi Mümessillik İç Ve Diş Tic. Ltd. Şti Notifikuotos įstaigos paslaugas teikiančios įmonės UDEM su Nr:2292 pagal 93/42/EEC Medicinos Priemonių Direktyvą

Ref. Nr.	Aprašymas	GMDN	Ref. Nr.	Aprašymas	GMDN
ID0510	Antimikrobinė plėvelė 5x10 cm	47783	ID4530	Antimikrobinė plėvelė 45x30 cm	47783
ID0607	Antimikrobinė plėvelė 6x7 cm	47783	ID4535	Antimikrobinė plėvelė 45x35 cm	47783
ID1012	Antimikrobinė plėvelė 10x12 cm	47783	ID4540	Antimikrobinė plėvelė 45x40 cm	47783
ID1020	Antimikrobinė plėvelė 10x20 cm	47783	ID4545	Antimikrobinė plėvelė 45x45 cm	47783
ID1030	Antimikrobinė plėvelė 10x30 cm	47783	ID4548	Antimikrobinė plėvelė 45x48 cm	47783
ID1050	Antimikrobinė plėvelė 10x50 cm	47783	ID4555	Antimikrobinė plėvelė 45x55 cm	47783
ID1060	Antimikrobinė plėvelė 10x60 cm	47783	ID4560	Antimikrobinė plėvelė 45x60 cm	47783
ID1520	Antimikrobinė plėvelė 15x20 cm	47783	ID4565	Antimikrobinė plėvelė 45x65 cm	47783
ID1528	Antimikrobinė plėvelė 15x28 cm	47783	ID4590	Antimikrobinė plėvelė 45x90 cm	47783
ID1530	Antimikrobinė plėvelė 15x30 cm	47783	ID5045	Antimikrobinė plėvelė 50x45 cm	47783
ID1620	Antimikrobinė plėvelė 16x20 cm	47783	ID5060	Antimikrobinė plėvelė 50x60 cm	47783
ID2010	Antimikrobinė plėvelė 20x10 cm	47783	ID5580	Antimikrobinė plėvelė 50x80 cm	47783
ID2020	Antimikrobinė plėvelė 20x20 cm	47783	ID5640	Antimikrobinė plėvelė 56x40 cm	47783
ID2030	Antimikrobinė plėvelė 20x30 cm	47783	ID5645	Antimikrobinė plėvelė 56x45 cm	47783
ID2040	Antimikrobinė plėvelė 20x40 cm	47783	ID5660	Antimikrobinė plėvelė 56x60 cm	47783
ID2525	Antimikrobinė plėvelė 25x25 cm	47783	ID5680	Antimikrobinė plėvelė 56x80 cm	47783
ID2815	Antimikrobinė plėvelė 28x15 cm	47783	ID5685	Antimikrobinė plėvelė 56x85 cm	47783
ID2830	Antimikrobinė plėvelė 28x30 cm	47783	ID5690	Antimikrobinė plėvelė 56x90 cm	47783
ID2840	Antimikrobinė plėvelė 28x40 cm	47783	ID5766	Antimikrobinė plėvelė 57x66 cm	47783
ID2845	Antimikrobinė plėvelė 28x45 cm	47783	ID6030	Antimikrobinė plėvelė 60x30 cm	47783
ID3020	Antimikrobinė plėvelė 30x20 cm	47783	ID6035	Antimikrobinė plėvelė 60x35 cm	47783
ID3027	Antimikrobinė plėvelė 30x27 cm	47783	ID6040	Antimikrobinė plėvelė 60x40 cm	47783
ID3030	Antimikrobinė plėvelė 30x30 cm	47783	ID6045	Antimikrobinė plėvelė 60x45 cm	47783
ID3035	Antimikrobinė plėvelė 30x35 cm	47783	ID6050	Antimikrobinė plėvelė 60x50 cm	47783
ID3040	Antimikrobinė plėvelė 30x40 cm	47783	ID6055	Antimikrobinė plėvelė 60x55 cm	47783
ID3045	Antimikrobinė plėvelė 30x45 cm	47783	ID6060	Antimikrobinė plėvelė 60x60 cm	47783
ID3050	Antimikrobinė plėvelė 30x50 cm	47783	ID6070	Antimikrobinė plėvelė 60x70 cm	47783
ID3060	Antimikrobinė plėvelė 30x60 cm	47783	ID6080	Antimikrobinė plėvelė 60x80 cm	47783
ID3535	Antimikrobinė plėvelė 35x35 cm	47783	ID6085	Antimikrobinė plėvelė 60x85 cm	47783
ID3540	Antimikrobinė plėvelė 35x40 cm	47783	ID6090	Antimikrobinė plėvelė 60x90 cm	47783
ID3545	Antimikrobinė plėvelė 35x45 cm	47783	ID6640	Antimikrobinė plėvelė 66x40 cm	47783
ID3550	Antimikrobinė plėvelė 35x50 cm	47783	ID6645	Antimikrobinė plėvelė 66x45 cm	47783
ID3560	Antimikrobinė plėvelė 35x60 cm	47783	ID6650	Antimikrobinė plėvelė 66x50 cm	47783
ID4030	Antimikrobinė plėvelė 40x30 cm	47783	ID6660	Antimikrobinė plėvelė 66x60 cm	47783
ID4035	Antimikrobinė plėvelė 40x35 cm	47783	ID6685	Antimikrobinė plėvelė 66x85 cm	47783
ID4040	Antimikrobinė plėvelė 40x40 cm	47783	ID6690	Antimikrobinė plėvelė 66x90 cm	47783
ID4042	Antimikrobinė plėvelė 40x42 cm	47783	ID9045	Antimikrobinė plėvelė 90x45 cm	47783
ID4045	Antimikrobinė plėvelė 40x45 cm	47783	ID9050	Antimikrobinė plėvelė 90x50 cm	47783
ID4060	Antimikrobinė plėvelė 40x60 cm	47783	ID9060	Antimikrobinė plėvelė 90x60 cm	47783
ID4528	Antimikrobinė plėvelė 45x28 cm	47783			

/antspaudas/

/parašas/

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Cp.

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 Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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 tvarsčiai, tvarstomoji medžiaga ir tvarsčiai, 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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 090237 0015 Rev. 01

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):

Gauze Dressings, Gauze Balls, Surgical Cloths, Covers, Surgical Gloves, Customized Surgical Procedure-Sets, Wound Dressings, Ropes

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713148089+713155324

Valid from: 2020-02-26
Valid until: 2024-05-26

Date, 2020-02-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

EC SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEC (MDD), Priedas II, išskyrus (4)
(IIa, IIb ar III klasės priemonės)

Nr. G1 090237 0015 Rev. 01

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):	**Marliniai tvarsčiai, marliniai tamponėliai, chirurginės medžiagos, apdangalai, chirurginės pirštinės, pagal užsakymą gaminami chirurginių procedūrų rinkiniai, žaizdų tvarsčiai, virvelės**

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 II Priedą. Ši kokybės užtikrinimo sistema apima gamybos aspektus, susijusius su atitinkamų priemonių / priemonių kategorijų sterilumo savybių išlaikymu ir atitinka šios direktyvos sąlygas. III klasės priemonių pardavimui reikalingas papildomas II priedo (4) sertifikatas. Taip pat žr. kitame lape.

Protokolo Nr.	713148089+713155324
Galioja nuo:	2020-02-26
Galioja iki:	2024-05-26

Data, 2020-02-26

/parašas/
Christoph Dicks
Sertifikavimo, Notifikuotos Įstaigos vadovas

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

NOBAMED Paul Danz AG

Declaration of Conformity
Konformitätserklärung
Medical Device Regulation (EU) 2017/745

We / Wir

NOBAMED Paul Danz AG
Höltkenstr. 1-5
D-58300 Wetter

declare in sole responsibility, that the product, this declaration refers to, correspond to the following procedures of conformity
erklären in alleiniger Verantwortung, dass das Produkt, auf das sich diese Erklärung bezieht, mit den folgenden Konformitätsbewertungsverfahren übereinstimmt.

SRN	**DE-MF-000000023**	
REF	**453407**	
Product/Produkt	**NOBAHEBAN® 4,5M 7,5 CM BRAUN**	
Basic UDI-DI	**403181549000**	**53**
Class/Klasse	**I**	
Rule/Regel	**1**	

Class I Annex I, II, III	**Klasse I Anhang I, II, III**
Class Is Annex XI, Part A	**Klasse Is Anhang XI, Teil A**
Class IIa, IIb, III Annex IX	**Klasse IIa, IIb, III Anhang IX**

according to the demands of the Medical Device Regulation (EU) 2017/745, 05 of April 2017.
gemäß der Bestimmung der Verordnung (EU) 2017/745 vom 05. April 2017.

Normative Requirements, Common Specifications and EC-Certificate numbers please see www.nobamed.com (search for REF number).
Normative Anforderungen, gemeinsame Spezifikationen und EC-Zertifikate Nummern siehe www.nobamed.com (Suche nach REF Nummer).
Our notified body is TÜV SÜD PS, Ridlerstr. 65, D-80339 München, 0123.
Unsere Benannte Stelle ist TÜV SÜD PS, Ridlerstr. 65, D-80339 München, 0123.

Person responsible for regulatory compliance/ Verantwortliche Person für die Einhaltung der Regulierungsvorschriften: Dr. A. Danz MBA, Executive Board NOBAMED Paul Danz AG. Wetter/ Ruhr, 13.04.21

Dr. Danz

/logotipas/

Atitikties deklaracija
Medicinos Priemonių Reglamentui (EU) 2017/745

Mes

NOBAMED Paul Danz AG
Höltkenstr. 1-5
D-58300 Wetter

Prisiimdami visą atsakomybę deklaruojame, kad produktas, esantis šioje deklaracijoje, atitinka šias atitikties procedūras

SNR	**Žr. dokumentą originalo kalba**	
REF	**Žr. dokumentą originalo kalba**	
Produktas	**Žr. dokumentą originalo kalba**	
Basic UDI-DI	**Žr. dokumentą originalo kalba**	**Žr. dokumentą originalo kalba**
Klasė	**Žr. dokumentą originalo kalba**	
Taisyklė	**Žr. dokumentą originalo kalba**	

Klasė I priedas I, II, III
Klasė Is Priedas XI, Dalis A
Klasė IIa, IIb, III Priedas IX

Pagal Medicinos Prietaisų Reglamento (EU) 2017/725, Balandžio 5 d, 2017 reikalavimus.

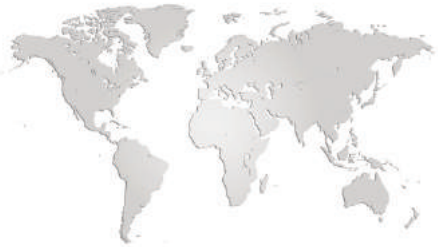
Normatyvinių reikalavimų , specifikacijų ir CE sertifikatų numerių ieškokite www.nobamed.com (ieškoti REF numerio)
Notifikuota Įstaiga TÜV SÜD PS, Ridlerstr. 65, D-80339 München, 0123.

Asmuo, atsakingas už norminių aktų laikymąsi: Dr. A. Danz MBA, Executive Board NOBAMED Paul Danz AG. Wetter/ Ruhr.

/parašas/

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

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

PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

Certified location:

Karl-Hall-Straße 1, 78187 Geisingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51268-Z3-00, the decision dated 2018-03-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-03-22 to 2023-03-21

Registration No.: 51268-16-02

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class II a (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIa	MD0101	37148 Laparoscopic sleeve MIS (Minimal Invasive Surgery) Systems:	EcoFlex Mod FlowSys Tube 1298-Series 1295-Series 1288-Series 1000-Series
IIa	MD0101 MDS7006	45342 Laparoscopic trocar sleeve anchor Balloon Systems for fixation; 1285-series modular disposable and 1283-/ 1284-Series fully disposable	EcoBalloon RA(-S) EcoBalloon URO(-S) EcoBalloon SB MonoBalloon RA(-S) MonoBalloon URO(-S) MonoBalloon SB VarioBalloon RA(-S) VarioBalloon URO(-S) VarioBalloon SB MonoBalloon Duo (DIL(-BI/XL) + RA/URO/SB) EcoBalloon Duo (DIL(-BI/XL) + RA/URO/SB)
IIa	MD0101	45342 Laparoscopic trocar sleeve anchor Modular Trocar System	TrocaStop TrocaCone Hasson Cone Fixation, abdominal wall
IIa	MD0101	37148 Laparoscopic sleeve Modular reusable systems	TrocaTec TrocaPort Reusable guide tube for trocar sleeve Reusable Modular Trocar Sleeve 1287-series
IIa	MD0101	45645 Laparoscopic sleeve seal Modular reusable systems	TrocaPort 1287-series
IIa	MD0101 MDS7006	45597 Trocar sleeve seal/port reducer Modular reusable systems: Disposable Valve Top	TrocaPort SEAL TrocaTec SEAL TrocaPort SEALSET TrocaTec SEALSET TrocaCap TrocaPort TOP TrocaReducer TrocaReducer L TrocaReducer S EcoBalloon TrocaPort MultiPort CAP 1287-series 1285-series
IIa	MD0101	45597 Trocar sleeve seal/ port reducer Modular reusable systems: Reusable valve top	TrocaTec Reducer sleeve Modular reusable trocar housing
IIa	MD0101 MDS7006	37148 Laparoscopic sleeve Modular disposable systems	TrocaSys 1289-series: TrocaSys SLEEVE

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIa	MD0101 MDS7006	42412 Laparoscopic trocar/sleeve Modular disposable systems	TrocaSys: TrocaSys SHIELD TrocaSys PYRAMID TrocaSys BLUNT TrocaSys PROTECT TrocaSys HASSON TrocaSys VIEW TrocaSys Double Kit TrocaSys Triple Kit TrocaSys Duo PROTECTTrocaSys Duo SHIELD TrocaSys Duo PYRAMID TrocaSys Duo BLUNT 1289-series
IIa	MD0101 MDS7006	42412 Laparoscopic trocar/sleeve	1282-Series MultiPort PROTECT MultiPort VIEW MultiPort CAP
IIa	MD0101 MDS7006	16833 Bone marrow biopsy procedure kit Cannula-trocar-system for biopsy of bone and bone Marrow	TrokaBone TrokaBone Sternal TrokaCut
IIa	MD0101 MDS7006	35886 Body aspiration needle, single-use Aspiration and injection needles of common hospital supply	Tapered needles -Chiba -Chiba Sono Dual Cannula System Triple Cannula Systems PTC
IIa	MD0101 MDS7006	47540 Soft-tissue biopsy needle, single-use Needles for core biopsy and aspiration	DeltaCut needle
IIa	MD0101 MDS7006	16835 Soft-tissue biopsy procedure kit, non-medicated	Dr. Steinhoff Kit
IIa	MD0101 MDS7006	61546 Nerve-locating anaesthesia needle Needles for peripheral nerve block	UniPlex UniPlex NanoLine KombiPlex B UniPlex NanoLine SURETY® SonoPlex STIM SonoPlex STIM SURETY®
IIa	MD0101 MDS7006	61547 Nerve-block sharp needle Needles for peripheral nerve block	SonoTAP SonoTAP NRFit SonoBlock MultiInject MultiInject Sono SonoMSK
IIa	MD0101 MDS7006	61546 Nerve-locating anaesthesia needle Needles for peripheral nerve block and catheter placement	SonoLong NanoLine SonoLong NanoLine Tuohy SonoLong NanoLine NRFit™ SonoLong NanoLine Tuohy NRFit™ PlexoLong NanoLine

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIa	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Needles/ trocars for needle-through-needle/ catheter-through-needle and initial puncture	IntroDucer Initial Puncture needle/ Pravaz Introducer 2.G Introducer SONO Introducer NRFit® GCS Guidance Instrument GLOA TIPPS-Placement needle
IIa	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Trocars for biopsy system	DeltaCut Trocar/ Coaxial Sleeve PrimoCut Trocar/ Coaxial Sleeve CoreCut Trocar/ Coaxial Sleeve
IIa	MD0101 MDS7006	58865 Vascular catheter introduction kit, non-steerable Needle/ kit for placement of central venous catheter	Vascular Sono Tsui E-IV
IIa	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Needles/ trocars for tunnelisation (e. g. of a catheter)	Split cannula/ Tearaway needle Indwelling Catheter/ Permanent Cannula
IIa	MD0101 MDS7006	46801 Subcutaneous catheter tunneler, single-use Needles/ trocars for tunnelisation (e.g. of a catheter)	Tunneler/ Awl
IIa	MD0101	46115 General-purpose catheter connector Adapter for catheter/ tube connection	Clamping Adapter (different colours) Clamping Adapter SURETY® Clamping Adapter NRFit®
IIa	MD0101 MDS7006	31245 Anaesthesia conduction filter Filter for injecting agents	Bacterial Filter 0,2 µm (LUER; SURETY®; NRFit® Filter 0,5 µm LUER; NRFit®)
IIa	MD0102 MDS7006	12750 Spring-loaded pneumoperitoneum needle, single-use Veress-Needle-Systems, fully disposable and disposable sharp outer needle for reusable modular system	Insufflation cannulae acc. Veress
IIa	MD0102	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, fully reusable System and reusable insufflation body for reusable modular system	Insufflation cannulae acc. Veress
IIa	MD0102 MDS7006	46669 Breast ductography cannula	Galactography kit
IIa	MD0102 MDS7006	33961 General surgical procedure kit, non-medicated, single-use Customized Procedure Kit for common hospital use	T-Pex Anchoring kit
IIa	MD0102 MDS7006	33069 Brachytherapy needle Needle for Seed placement and implantation	DeltaSeed DeltaFix

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIa	MD0102 MDS7006	47714 Subdermal needle Electrode Needles for injection of Botulinumtoxin	Bo-Inject-Series: Bo-NanoInject Bo-Inject-Series: Bo-SonoInject Bo-Inject-Series: Stimulation-Cable for needle, Accessory
IIa	MD0102 MDS7006	45130 Tissue extraction bag	Resection Bag
IIa	MD0102 MDS7006	58742 Wound drainage bag	MultiPort Bag
IIa	MD0102 MDS7006	35824 Closed-wound drainage kit, general-purpose	Quadrain F10 Quadrain F12 Quadrain F15
IIa	MD0102 MDS7006	10817 Pleural drainage system	Pleura Puncturing Kit
IIa	MD0102 MDS7006	46328 Simple pneumoperitoneum needle Veress-Needle-Systems, semi-Reusable	Insufflation cannulae acc. Veress
IIa	MD0102 MDS7006	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, Semi-reusable, initially sterilized	Insufflation cannulae acc. Veress
IIa	MD0102 MDS7006	47017 General-purpose syringe, single-use Injection syringes, different volumes	Injection Syringes NRFit® LOCK
IIa	MD0102 MDS7006	61513 Endoscopic gel implant needle	Tapered cannula – VUR
IIa	MD0102 MDS7006	16858 Catheter injection port	Injection tube, Y-tube
IIa	MD0102 MDS7006	35375 Stopcock	Stopcock/ 3-way-valve
IIa	MD 0102 MDS7006	47191 Anesthesia conduction catheterization kit Set for aerosole anaesthesia	Kit “Spray as you go set”
IIa	MD0105 MDS7006	46910 Ophthalmic cannula, infusion Augenkanüle nach Atkinson	SonoEye
IIa	MD0106	60417 Surgical instrument cleaning adaptor	Cleaning Adapter LUER, LUER LOCK
IIa	MD0106	47829 Surgical instrument handle Handles for Suction-Irrigation Systems	FlowSys Eco FlowSys Twin FlowSys FlowSys ACCESS Valve Handle Pistol Handle FlowSys Ergo
IIa	MD0106	12291 Rigid optical Laparoscope Optical Endoscopes/ Laparoscopes	502-series

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIa	MD0106 MDS7006	44794 Surgical balloon dissector Balloon Systems for distension, 1285-series modular disposable and 1284-Series fully disposable	Eco Balloon DIL EcoBalloon DIL-XL EcoBalloon DIL-BI MonoBalloon DIL MonoBalloon DIL-XL MonoBalloon DIL-BI
IIa	MD0204 MDS7006	40808 Implantable lesion localization marker Mammography Localisation-Puncturing-kit	MammaLoc SONO MammaLocalization Kit

Class II a (active):

Class	MD-Code	GMDN	Brand
IIa	MD1103	35723 Nerve-locating system, battery-powered Nerve stimulator for nerve and muscle localization	MultiStim ECO MultiStim SWITCH MultiStim SENSOR
IIa	MD1104 MDS7006	58990 Side-notch biopsy gun, single-use Automated Disposable Biopsy System with/ without trocar	CoreCut PrimoCut
IIa	MD1104	22724 Side-notch biopsy gun, reusable Biopsy System: Reusable gun and disposable needles with/ without trocar	DeltaCut

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class II b (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD0101 MDS7006	46383 Nerve-locating anaesthesia kit, continuous-administration Pre-Assembled Procedure Kit for peripheral Nerve Block with/ without stimulation	PlexoLong PlexoLong SONO NanoLine acc. Meier PlexoLong NanoLine PlexoLong NanoLine acc. Meier PlexoLong Seldinger SonoLong Sono NanoLine SonoLong Echo NanoLine (incl. Paediatric) SonoLong Curl Echo (incl Paediatrics) SonoLong Sono NanoLine NRFit® SonoLong Echo NanoLine (incl. Paediatric) NRFit® SonoLong Curl Echo (incl Paediatrics) NRFit® StimuLong Plus StimuLong NanoLine StimuLong NanoLine acc. Kick StimuLong SONO StimuLong Sono NanoLine StimuLong Sono II NanoLine MultiSet KombiPlex B E-Cath acc. Tsui E-Cath Plus acc. Tsui
IIb	MD0101 MDS7006	46383 Nerve-locating anaesthesia kit, continuous-administration Customized Procedure Kit for peripheral Nerve Block with/ without stimulation	001151-Series 181151-Series 531156-Series 531157-Series 521185-Series 531185-Series
IIb	MD0101 MDS7006	46382 Nerve-locating anaesthesia kit, single-administration Customized Procedure Kit for peripheral Nerve Block with/ without stimulation	001151-Series 001157-Series 001185-Series 061151-Series 071151-Series
IIb	MD0101 MDS7006	34840 Anaesthesia kit, brachial plexus Pre-Assembled Procedure Kit/ System for peripheral Nerve Block	PlexoLong PeriLong PeriLong
IIb	MD0101 MDS7006	47191 Anaesthesia conduction catheterization kit Pre-assembled kits for wound infiltration/ infiltration analgesia	InfiltraLong-Series (900, 900T, 400, 400T, 420, 410T, 500, 500T, 600, 600T, 700, 700T) InfiltraLong SONO-Series (420, 420T, 500, 500T, 600, 600T, 900, 900T) InfiltraLong TUN-series (420T, 500T, 600T, 700T, 900T) InfiltraLong DUO-Series InfiltraLong Forte-series Fuser Pump Kit-Series (500, 600, 700, 900) FuserPump Forte series InfiltraLong- NRFit® Series (900, 900T, 400, 400T, 420, 410T, 500, 500T, 600, 600T, 700, 700T) InfiltraLong SONO- NRFit®-Series (420, 420T, 500, 500T, 600, 600T, 900, 900T)

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
			InfiltraLong TUN- NRFit®-series (420T, 500T, 600T, 700T, 900T) InfiltraLong DUO- NRFit®-Series Fuser Pump Kit- NRFit®-Series (500, 600, 700, 900) FuserPump Forte NRFit®-series
IIb	MD0101 MDS7006	47191 Anaesthesia conduction catheterization kit Pre-assembled Procedure Kit for peripheral Nerve Block	FASCIA ILIACA Block Rectus Sheath Block SonoTAP Dual Katheter Set
IIb	MD0101 MDS7006	16430 Anaesthesia conduction catheter Peripheral catheters for continuous anaesthesia and analgesia	PlexoLong Cath StimuLong Cath Plexus Cath SonoLong Curl ECHO Cath Peripheral standard catheter Peripheral coiled catheter Peripheral stimulation catheter Peripheral coiled stimulation catheter Catheter Seldinger technique
IIb	MD0102 MDS7006	16472 Cement dispenser, orthopaedic Systems/ Kits for cement injection (Cementoplasty, cyphoplasty, vertebroplastie)	Kit for Cemento reusable Gun Kit for/ with Cemento disposable gun 1385-Series 1395-Series
IIb	MD0102 MDS7006	47737 Orthopaedic cement injection cannula Disposable needles for cement injection	Special-Vertebroplasty Cannula acc. To Gangi, Needles/ cannulas/ Trocars for Cemento disposable gun Needles/ cannulas/ Trocars for Cemento reusable gun 1394-Series 1384-Series 1392-Series 1393-Series 1382-Series
IIb	MD0106 MDS7006	46542 Elastomeric infusion pump system	FuserPump FuserPump NRFit

Class II b (active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD 0102 MDS7006	58739 - Radio-frequency ablation system probe cannula, single-use Thermolesion needles, cannulas and trocars for RF-Ablation	RFTL Needle RFTL SONO Thermolesion needle/ cannula RGN needle/ cannula
IIb	MD1104	33596 Endoscopic electrosurgical coagulator/cutter, unipolar, reusable Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C J-Hook Right Angle (90°) 45° angle Needle Spatula Ballpoint

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
			Conical 1299-Series 2000-series (standalone, integrated handle)
IIb	MD1104	35732 Rigid endotherapy biopsy forceps, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoTop biopsy punch, serration biopsy punch biopsy punch, spoon shaped Biopsy spoon forceps with fixation thorn Biopsy punch, spoon shaped, fixation thorn Biopsy Kit 1292-Series
IIb	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoClamp ErgoTop BABCOCK COLLIN MONTGOMERY KOCHER DE BAKEY MultiTip MARYLAND Universal Claw type DOLPHIN Reservoir Atraumatic OVIDUCT MOUSE TOOTH ALLIGATOR MIXTER ALLIS MAXI GRIP DORSEY MultiTip ENDOCLINCH KELLY AGGRESSIVE RETRACTION DUCKBILL Grasper Kit Scissor Kit Scissor kit MonoTip Clamping Kit 1292-Series 1293-Series
IIb	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip MARYLAND MonoTip ENDOCLINCH
IIb	MD1104	37148 Laparoscopic sleeve HF and SI Systems:	FlowTube HF FlowTube HF-C 1299-Series

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Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MultiTip METZENBAUM (M, L, S, P) ErgoScissors ErgoTop Dissection SCISSORS curved/ straight Dissection SCISSORS METZENBAUM Hook Type SCISSORS Hooked Scissors METZEMBAUM Micro Scissors curved/ straight Peritoneal Scissors curved/ straight Fine Serration Curved Surgical scissors Wondercut Metzenbaum Soft Surgical Spoon Scissor Kit 1292-Series 1293-Series
IIb	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM M
IIb	MD1104 MDS7006	58949 General-purpose surgical scissors, single-use Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM L MonoTip METZENBAUM M MonoTip METZENBAUM S MonoTip METZENBAUM P Scissor Kit
IIb	MD1104	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C 1299-Series 2000-series (standalone, integrated handle)
IIb	MD1104 MDS7006	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	1299-Series FlowTube HF RET
IIb	MD1104	12726 Needle holder, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoNeedle ErgoSys Needle Holder Kit 1292-Series 1000er series

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD1104	47829 Surgical instrument handle Handles for Suction-Irrigation/ HF-Systems	EcoGrip Mod ErgoFlex ErgoGrip EcoFlex EcoGrip EcoGrip-M EcoGrip-F FlowSys Eco HF FlowSys Ergo HF FlowSys Twin HF FlowSys HF TipRatchet TipHandle Pistol Handle Lever Valve Valve Handle Trumpet Valve Handle Double Trumpet Valve Handle1292-Series 1293-series 1299-series 1000er-series
IIb	MD1104	11798 Utility forceps, reusable Modular inserts with integrated rod	Endo hook, fan shaped
IIb	MD1104	38661 Rigid endoscopic grasping forceps, reusable MIS-HF-System	ErgoSys Scissor Kit
IIb	MD1104	33596 Endoscopic electrosurgical coagulator/cutter, unipolar, reusable MIS-HF-System: Connection Rods, guide tubes	TipRod Eco TipRod Ergo TipTube ErgoTube

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

Class III:

Class	MD-Code	GMDN	Brand or item code group
III	Cannulas for regional anaesthesia at the central nervous system (epidural, spinal, combined spinal-epidural (CSE))		
	MD0101 MDS7006	58293 - Epidural needle, non-threaded	Tuohy Tuohy SONO Tuohy SURETY® Tuohy NRFit® Tuohy NanoLine
			SPROTTE SPECIAL SPROTTE® SPECIAL NRFit®
		35212 - Spinal needle, single-use Spinal needle for anaesthesia/ analgesia conduction and lumbar puncture	SPROTTE® STANDARD SPROTTE® Curved SPROTTE® Tapered SPROTTE® Tapered NRFit® SPROTTE® SONO SPROTTE® STANDARD 2.G SPROTTE® SONO 2.G SPROTTE® STANDARD SURETY® SPROTTE® STANDARD NRFit® Crawford/ CauDal Needle Quincke Quincke SONO Quincke NRFit® Quincke SURETY®
III	Cannulas for lumbar puncture and myelography at the central nervous system		
	MD0101 MDS7006	35212 - Spinal needle, single-use Needles for diagnostic lumbar puncture (injection, aspiration)	SPROTTE® STANDARD SPROTTE® STANDARD SONO SPROTTE® STANDARD SURETY® SPROTTE® STANDARD NRFit® Quincke Quincke SONO Quincke NRFit® Quincke SURETY®
III	Cannulas and special cannulas for analgesia at the central nervous system		
	MD0101 MDS7006	35212 - Spinal needle, single-use Spinal needle for anaesthesia/ analgesia conduction	Chiba
III	Catheter for regional anaesthesia, spinal, epidural at the central nervous system (CNS)		
	MD0101 MDS7006	16430 Anaesthesia conduction catheter Spinal and epidural catheters for continuous anaesthesia and analgesia	EpiLong CATH EpiLong CATH SURETY® CNS standard catheter CNS coiled catheter CNS stimulation catheter CNS coiled stimulation catheter with adapter to: CNS catheter NRFit® CNS coiled catheter NRFit® CNS catheter SURETY®

Annex to the EC Certificate No. 51268-16-02

Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

III	Kits for regional anaesthesia contacting the central nervous system		
	MD0101 MDS7006	34842 - Epidural anaesthesia kit, non-medicated Pre-Assembled Procedure Kit for continuous epidural Anaesthesia	EpiLong EpiLong I EpiLong II EpiLong Soft EpiLong Soft Sono StimuLong Sono Tsui Tuohy NRFit® EpiLong NRFit® EpiLong SURETY®
		34842 - Epidural anaesthesia kit, non-medicated Customized Procedure Kit for continuous epidural Anaesthesia	001151-Series 021151-Series 0431157-Series 061151-Series 071151-Series 091151-Series 151151-Series 211151-Series 221151-Series
		46308 - Epidural/ intrathecal anaesthesia kit Pre-Assembled Procedure Kit for combined spinal- epidural Anaesthesia	EpiSpin II Safety EpiSpin Lock EpiSpin Lock Soft EpiSpin SAFTEY SOFT EpiSpin SURETY® EpiSpin Soft NRFit®
		46308 - Epidural/ intrathecal anaesthesia kit Customized Procedure Kit for combined spinal- epidural Anaesthesia	001151-Series 071151-Series 181151-Series 211151-Series 221151-Series
		34845 - Intrathecal anaesthesia kit Pre-Assembled Procedure Kit for spinal Anaesthesia	IntraLong SPROTTE® SURETY® SPROTTE® NRFit®
		34845 - Intrathecal anaesthesia kit Customized Procedure Kit for spinal Anaesthesia	001151-Series 001251-Series 051151-Series 061151-Series 071151-Series 071152-Series 121151-Series 141151-Series 151151-Series 181151-Series 191151-Series 211151-Series 221151-Series 231151-Series

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Revision status: 0

Valid from 2018-03-22 to 2023-03-21

Devices/device categories included in the certificate:

III	Cannulas, Special cannulas and treatment units for navigated and manual brain biopsy		
	MD0101 MDS7006	38563 Brain biopsy procedure kit Cannula system for stereotactic and navigated brain biopsy	BrainPro DBZ Sedan BrainPro Access

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-03-20
Notified Body ID-number: 0124

CE kokybės užtikrinimo sertifikatas

Pagal 93/42/EEC Direktyvos II Priedą išskyrus 4 skirsnį

Europos sąjungos notifikuota įstaiga DEKRA Certification GmbH
patvirtina, kad gamintojo

PAJUNK GmbH Medizintechnologie

Karl-Hall-Strasse 1 – 78187 Geisingen, Vokietija

Medicinos tikslais taiko kokybės užtikrinimo sistemą pagal Direktyvos 93/42 / EEB II priedą prietaisams, kurie yra išvardinti preide. Patvirtinimas grindžiamas pakartotinio sertifikavimo audito ataskaitos Nr.51268-Z3-00, sprendimas priimtas 2018-03-20 ir galioja tik sėkmingai vykdant metinius preižiūros auditus.

Sertifikatas galioja nuo 2018 03 22 iki 2023 03 22

Registracijos numeris: 51268-16-02

/Parašas/
Dekra Certification GmbH
Stuttgart, 201-03-22

Notifikuotas įstaigos nr: 0124

CE sertifikato Nr. 51268-16-02 priedas

Patikrinimų skaičius:0
Galioja: nuo 2018-03-22 iki 2023-03-21
Į sertifikatą įtrauktos preimonės / priemonių ketegorijos:

Klasė	MD-kodas	GMDN	Pavadinimas / variantai / elemento kodų grupė
IIa	MD0101 MDS7006	45018 neimplantuojami adatų pravedėjai, vienkartiniai Adatos / trokarai adatai įvesti / kateteriui įvesti ir pradinei punkcijai	Introducer Initial Puncture bneedle/ Pravaz Introducer 2.G Introducer Sono GCS pravedimo instrumentas TIPPS- adata
IIa	MD0101 MDS7006	45018 neimplantuojami adatų pravedėjai, vienkartiniai	DeltaCut Trocar/ Coaxial Sleeve PrimoCut Trocar/ Coaxial Sleeve CoreCut Trocar/ Coaxial Sleeve
IIa	MD0101 MDS7006	58865 Vaskularnis katetrio įvedimo rinkinys Adata/ rinkinys įvesti centrinės venos kateteriui	Vascular Sono Tsui E-IV
IIa	MD0101 MDS7006	45018 neimplantuojami adatų pravedėjai, vienkartiniai Adatos?trokarai nuleizavimui	Padalijama kaniulė / „Tearaway“ adata Vidinis kateteris / Nuolatinė kaniulė

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products:
- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls (with or without X-ray thread)
- Sterile and non-sterile gauze rolls (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump
- Sterile endotracheal tubes
- Sterile tracheostomy tubes

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:

ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Venturi masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizers
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use
- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Swiątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:

ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves
- Sterile procedure kits

For the following medical devices the scope covers only the aspects of the manufacture concerned with securing and maintaining sterile conditions:

- Elastic bandages
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Alginate dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Swiątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:

ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Fluid collection pouches
- Nelaton catheters
- Vaginal speculums
- Cervical brushes
- Urine bags
- Enema bags
- Tongue depressors
- Oropharyngeal airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Cannula stoppers
- Umbilical cord clamps

Replaces EC Certificate, Registration No.: DD 60139535 0001

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Activity: Final inspection and release.
/02	ZARYS International Group Spółka z o.o. sp.k ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Activity: Final inspection and release.

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139535 0001

Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs
  (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges
  (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls
  (with or without X-ray thread)
- Sterile and non-sterile gauze rolls
  (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
  (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 2/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 3/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 4/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannulla fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 5/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity: Production

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

CE sertifikatas
93/42/EEC Direktyva V Priedas
Gamybos kokybės užtikrinimas
Medicinos prietaisai

Registracijos Nr.: DD 60139535 0001

Ataskaitos Nr.: 26300232 017

Gamintojas: Zarys International Group
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Produktai: (Žr. Priedus dėl produktų ir įtrauktų vietų)
Pakeičia CE sertifikatą Nr. DD 60100191 0001

Galioja iki: 2024-05-27

Notifikuota įstaiga patvirtina minėtos įmonės įdiegtą ir taikomą kokybės valdymo sistemą. Direktyvos 93/42/EEB V Priedo reikalavimai buvo įvykdyti. Minėtas gamintojas yra įdiegės ir taiko kokybės užtikrinimo sistemą, kuri yra periodiškai tikrinama, pagal minėtos direktyvos V Priedo 4 skyrių. IIb ir III klasės prietaisų, minimų šiame sertifikate, perkėlimui į rinką būtinas EB tipo patikros sertifikatas pagal III Priedą.

Galioja nuo: 2019-06-09

Notifikuota įstaiga

/parašas/ /antspaudas/

Data: 2019-05-27

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg

TÜV Rheinland LGA Products GmbH yra Notifikuota įstaiga pagal Direktyvą 93/42/EEB dėl medicinos prietaisų, kurios identifikavimo numeris: 0197.

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterili ir nesterili kerpama marlė
- Nesterilūs marliniai tvarsčiai
- Sterilus/nesterilus marlinis tvarstis

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs marlės rutuliai

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs marlės ritiniai

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs neaustinės medžiagos tvarsčiai

(su/be rentgenokontrastine linija)

- Sterilūs parafininiai tvarsčiai
- Sterilūs trijų krypčių kraneliai
- Sterilios vienkartinės transfuzinės sistemos
- Sterilios vienkartinės infuzinės sistemos
- Sterilios prailginimo linijos infuzinėms pompoms

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterilūs endotrachėjiniai vamzdeliai
- Sterilūs tracheostominiai vamzdeliai
- Sterilio kvėpavimo grandinės
- Sterilūs prailgintojai prie intub. Vamzdelio
- Sterilios laringinės kaukės
- Sterilios deguonies kaukės
- Sterili kaukė su rezervuaru
- sterili aerozolinė kaukė
- Sterlios nosies deguonies kaniulės
- Sterilūs aerozoliniai rinkiniai
- Sterilūs deguonies vamzdeliai
- Sterilūs atsiurbimo kateteriai
- Sterilūs chirurginiai atsiurbimo rinkiniai
- Sterilios chirurginės atsiurbimo kaniulės
- Sterilūs maitinimo zondai
- Sterilūs skrandžio ir duodenaliniai zondai
- Sterilūs urologiniai kateteriai
- Sterilūs vienkartiniai švirkštai

Data: 2019-05-27 **Notifikuota įstaiga**

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterilūs insulininiai švirkštai
- Sterilūs tuberkuliniai švirkštai
- Sterilios hipoderm· nės adatos
- Sterilios insulininių penų adatos
- Sterilūs kraujo lancetai
- Sterilios intraveninės kaniulės
- Sterilūs beadatiniai vožtuvai
- Sterilios chirurginės pirštinės

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Žemiau nurodytiems medicinos prietaisams reikalavimai taikomi tik gamybos aspektams, susijusiems su sterilių sąlygų kūrimų bei išlaikymu:

- Lipnus kaniulių fiksatoriai
- Lipnūs žaizdų tvarsčiai
- Akių tamponėliai
- Pjūvio juosta
- Permatomi juostiniai tvarsčiai
- Putų tvarsčiai
- Absorbuojantys žaizdų tvarsčiai
- Chirurginiai chalatai
- Chirurginiai dangalai
- Skysčių rinkimo talpos
- Nelaton kateteriai

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:
Žemiau nurodytiems medicinos prietaisams reikalavimai taikomi tik gamybos aspektams, susijusiems su sterilių sąlygų kūrimų bei išlaikymu:

- Vaginalinės spekulės
- Gimdos kaklelio šepetėliai
- Šlapimo maišeliai
- Liežuvio prispaudėjai
- Orofaringiniai vamzdeliai
- Intubaciniai stiletai
- Tracheostominio vamzdelio laikikliai
- Atsiurbimo vamzdeliai
- Ištraukimo kaniulės
- Alignato tvarsčiai
- Kaniulių kamštukai
- Umbilikaliniai spaustukai

Data: 2019-05-27 **Notifikuota įstaiga**

/parašas/ /antspaudas/

Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60139535 0001**

Ataskaitos Nr.: **26300232 017**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtrauktos vietos:

Zarys International Group
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Lenkija

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski