# EG-Zertifikat / *EC-Certificate*

## gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

**Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.**
**Osmangazi Mahallesi, Gazi Caddesi No: 21,**
**Esenyurt 34522 İstanbul**
**Türkiye**

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
*for the products / product category: List of products see annex 1*

**Medizinische Einmalartikel und Absauggeräte**
***Disposable medical devices and devices for aspiration and vacuum extraction***

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

*has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.*

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-16
bis / *until* 2023-09-16
Edition 8

Zertifizierungsstelle für Medizinprodukte
*Certification body for medical devices*

Essen, 2020-04-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
*Products of class IIb*

Pressure Monitoring Set
Leukocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
*Products of class IIa*

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
*Certification body for medical devices*

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
*Products of class IIa*

Tourniquet Set
IV Cannula
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannula
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
*Certification body for medical devices*

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**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
*Products of class IIa*

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line
External Drainage Set
Vent Catheter
Vessel Cannula
Coronary Artery Retraction Clips

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
*Certification body for medical devices*

Essen, 2021-05-25

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
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**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
*Products of class Is (sterile)*

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
*Certification body for medical devices*

Essen, 2021-05-25

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**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
*Products of class Is (sterile)*

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

**Anmerkung:** Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
***Note:*** *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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*Certification body for medical devices*

Essen, 2021-05-25

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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**ZLG-BS-236.10.16**

# ANLAGE / *ANNEX*



## Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
*Products of class Im (with measuring function)*

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

**Anmerkung:** Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
***Note:*** *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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www.zlg.de
**ZLG-BS-236.10.16**

# CE Sertifikatas

## Remiantis 93/42/EEC direktyvos, II Priedu **(be 4 skyriaus)**

Patvirtinama, kad įmonė

**Bicakcilar Tibbi Cihazlar Sanayi ve Ticaret A. S.**
**Osmangazi Mahalleso, Gazi Caddesi Nr. 21,**
**Esenyurt 34522 Stambulas, Turkija**

Produktams/produktų kategorijoms: sąrašas pateikiamas 1 Priede

**Vienkartiniams medicininiams prietaisams, kvėpavimo ir vakuumo ekstrakcijos prietaisams**

Įdiegė kokybės sistemą kūrimui, gamybai ir galutinei apžiūrai, remiantis 93/42/EEC direktyvos II Priedo reikalavimais (išskyrus 4 skyrių). CE žymėjimui reikalingas papildomas notifikuotos įstaigos notifikavimo numeris. Sertifikato galiojimas paremtas kokybės valdymo sistemos priežiūra atliekama remiantis direktyvos reikalavimais ir jo stebėsena (atliekama notifikuotos įstaigos, pagal II Priedo skyrių 5). Šis sertifikatas negali būti perduodamas jokiomis sąlygomis.

Registracijos Nr. 04 232 980886
Ataskaitos Nr. 3524 7139
3526 6208
3526 6290

Galioja nuo: 2020-04-16

Galioja iki: 2023-09-16

8 leidimas

/parašas/

Essen, 2020-04-16

# PRIEDAS



## Reg.Nr. 04 232 980886

*IIb klasės produktai*

Slėgio kontrolės rinkinys
Leukocitų filtrų sistema
Gama leukocitų filtro rinkinys

*IIa klasės produktai*

Krūtinės ląstos punkcijos rinkinys
Krūtinės ląstos kateteris
Arterinė adata
Endotrachėjinis vamzdelis
Nasogastrinis kateteris
Skrandžio kateteris
Maitinimo kateteris
Slėgio matuoklis
3-jų padėčių kranelis

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Notifikuojančios insitucijos identifikavimo Nr. 0044

**Notifikuota**
**Pripažinta**
**ZLG, ZLS: www.zlg.de**

# PRIEDAS



## Reg. Nr. 04 232 980886

*IIa klasės produktai*

Timpų rinkinys
IV kaniulė
Atsiurbimo kateteris
Mikroagregato filtrų rinkinys (Kraujo filtrų rinkinys)
„Soft Dren“
Deguonies kateteris
Nosies deguonies kaniulė
Deguonies jungiamasis vamzdelis
Tracheostomijos vamzdelis
Ekstrakorporiniai PVC vamzdeliai
Ekstrakorporinių vamzdelių rinkinys
„Quick Prime“ sistema
Kardioplegijos sistema
Žaizdų drenavimo sistema
Infuzijos pompų sistema
„Yankauer“ atsiurbimo sistema
Atsiurbimo jungiamieji vamzdeliai
Chirurginis pintas ruloninis pleistras
Nelatono kateteris
„Tiemann“ kateteris

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

# PRIEDAS

Priedas 1, puslapis 3 iš 6

## Reg.Nr. 04 232 980886

*IIa klasės produktai*

Hidrofilinis dengtas šlapimo kateteris
IV filtrų sistema
Aspiratoriai
Kraujo perpylimo sistema
Rektalinis kateteris
Umbilikalinis kateteris
Angiografijos rinkinys
B-Soft rinkinys
Aortos iškandėjas (perforatorius)
Dujų mėginių ėmimo linija
Išorinio drenažo rinkinys
Ventrikulinis kateteris
Kraujagyslių kaniulė
Vainikinių arterijų skėtiklis

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

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**Pripažinta**
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# PRIEDAS

Priedas 1, puslapis 4 iš 6

## Reg.Nr. 04 232 980886

*Is klasės produktai (sterilūs)*

Šlapimo surinkimo maišelis
Plaeuros drenavimo sistema
Centrinės venos slėgio sistema
„Guedel“ kvėpavimo takų prietaisas
Čiaupas
Prailginimo linijos
„Kapkon“ sujungiklis
Tiesus sujungiklis
Tiesus „Luer“ sujungiklis
Y sujungiklis
Y „Luer“ sujungiklis
Stabdiklis
Stabdiklis (Instopper)
Bambagyslės spaustukas
Ūžšlaplinės rezekcijos (T.U.R.) sistema/Artroskopijos sistema
Perpylimo sistema
Intraveninės infuzijos sistema
Intraveninės infuzijos sistema/ Tėkmės matuoklis
Intraveninės infuzijos sistema/ Biuretė

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Notifikuojančios insitucijos identifikavimo Nr. 0044

**Notifikuota**
**Pripažinta**
**ZLG, ZLS: www.zlg.de**

# PRIEDAS

Priedas 1, puslapis 5 iš 6

## Reg.Nr. 04 232 980886

Is klasės produktai (sterilūs)

„B-Safe“ rinkinys
Intubacijos stiletas
„Combi“ stabdiklis
Urimetras
Krūtinės ląstos drenavimo sistema
Vaginalinis skėtiklis
Klizmavimo sistema
I.V. infuzijos rinkinys su/be srovės reguliatoriumi
Kontrolinis švirkštas
Mekonijaus aspiratorius konektorius

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

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Notifikuojančios insitucijos identifikavimo Nr. 0044

**Notifikuota**
**Pripažinta**
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# PRIEDAS



## Reg.Nr. 04 232 980886

*Im klasės produktai (su matavimo funkcija)*

Urimetras
Centrinės venos slėgio (CVP) sistema
Pleuros drenavimo sistema
Treniruoklis plaučių tūriui (B-Spiro)
Infuzijos sistema su biurete
Krūtinės ląstos drenavimo sistema

**Pastaba**: Sertifikavimo sistema yra apribota gamybos aspektų, susijusių su prietaisų metrologinių savybių atitikimu I klasės priemonėms su matavimo funkcija.

Protokolo Nr. 3529 1130

Galioja nuo 2021-05-25
Leidimas 16

/Parašas/

Medicinos priemones sertifikuojanti institucija

Essen, 2021-05-25

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**Notifikuota**
**Pripažinta**
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Benannt durch/Designated by
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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 093294 0002 Rev. 02**

**Manufacturer**

**Changzhou Cornwall Medical Devices Co., Ltd.**
Yincun, Zouqu Town
Zhonglou District
213147 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Changzhou Cornwall Medical Devices Co., Ltd.
Yincun, Zouqu Town, Zhonglou District, 213147 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**

**Urine Bag, Infant Urine Collection Bag, Negative Pressure Suction Liner, Saliva Ejector, Yankauer Suction Tip, Connecting Tube, Oropharyngeal Airway, Vaginal Speculum, Umbilical Cord Clamp, ID Bracelet, Rectal Tube, Sterile Syringe for Single Use (without Needle)**

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.:** SH19989EXT01

**Valid from:** 2020-01-22
**Valid until:** 2024-05-26

**Date,** 2020-01-22

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

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

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
## No. 2022-MDR/QS-026

**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: Sterile Syringes for Single Use**
**(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-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Hypodermic Syringe for Single use | CHIRANA | 2part syringe – Luer – 2ml | CH002L |
| | | 2part syringe – Luer – 5ml | CH005L |
| | | 2part syringe – Luer – 10ml | CH010L |
| | | 2part syringe – Luer – 20ml | CH020L |
| | | 3part syringe – Luer – 1ml | CH03001L |
| | | 3part syringe – Luer – 2ml | CH03002L |
| | | 3part syringe – Luer – 3ml | CH03003L |
| | | 3part syringe – Luer – 5ml | CH03005L |
| | | 3part syringe – Luer – 10ml | CH03010L |
| | | 3part syringe – Luer – 20ml | CH03020L |
| | | 3part syringe – Luer – 30ml | CH03030L |
| | | 3part syringe – Luer – 50ml | CH03050L |
| | | 3part syringe – Luer-Lock – 1ml | CH03001LL |
| | | 3part syringe – Luer-Lock – 2ml | CH03002LL |
| | | 3part syringe – Luer-Lock – 3ml | CH03003LL |
| | | 3part syringe – Luer-Lock – 5ml | CH03005LL |
| | | 3part syringe – Luer-Lock – 10ml | CH03010LL |
| | | 3part syringe – Luer-Lock – 20ml | CH03020LL |
| | | 3part syringe – Luer-Lock – 20ml – Opaque | CH03020LLO |
| | | 3part syringe – Luer-Lock – 30ml | CH03030LL |
| | | 3part syringe – Luer-Lock – 50ml | CH03050LL |
| | | 3part syringe – Luer-Lock – 50ml – Opaque | CH03050LLO |
| Sterile Hypodermic Syringe for Single use | ECOJECT | 2part syringe – Luer – 2ml | 20002 |
| | | 2part syringe – Luer – 5ml | 20005 |
| | | 2part syringe – Luer – 10ml | 20010 |
| | | 2part syringe – Luer – 20ml | 20020 |



Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarina 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-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Injection Set for Single Use | CHIRANA | 2ml with needle 0,60 x 30 mm | CH002L0630 |
| | | 2ml with needle 0,70 x 30 mm | CH002L0730 |
| | | 5ml with needle 0,70 x 30 mm | CH005L0730 |
| | | 5ml with needle 0,70 x 35 mm | CH005L0735 |
| | | 10ml with needle 0,80 x 40 mm | CH010L0840 |
| | | 20ml with needle 0,80 x 40 mm | CH020L0840 |
| | | 2ml with needle 0,60 x 25 mm | CH03002L0625 |
| | | 2ml with needle 0,60 x 30 mm | CH03002L0630 |
| | | 2ml with needle 0,70 x 30 mm | CH03002L0730 |
| | | 2ml with needle 0,80 x 40 mm | CH03002L0840 |
| | | 5ml with needle 0,60 x 25 mm | CH03005L0625 |
| | | 5ml with needle 0,70 x 30 mm | CH03005L0730 |
| | | 5ml with needle 0,70 x 35 mm | CH03005L0735 |
| | | 10ml with needle 0,80 x 40 mm | CH03010L0840 |
| | | 20ml with needle 0,80 x 40 mm | CH03020L0840 |
| | | 50ml Luer with needle 1,20 x 40 mm | CH03050L1240 |
| | | 50ml Luer-Lock with needle 2,0 x 30 mm – transparent | CH030502030LL |
| | | 50ml Luer-Lock with needle 2,0 x 30 mm – opaque | CH030502030LLO |



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-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| **Sterile Injection Set for Single Use** | **SYRISET** | 1ml with needle 0,45 x 12 mm and filter<br>1ml with needle 0,5 x 16 mm and filter<br>2ml with needle 0,45 x 12 mm and filter<br>2ml with needle 0,5 x 16 mm and filter | 10100<br>10200<br>10300<br>10400 |

**Versions (CHIRANA / SYRISET):**

Combination a), b) and c)

a) Syringe (2-part / 3-part, Luer / Luer-Lock)
1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30 ml, 50ml

b) Needle (14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G)
0.3x12, 0.3x40,
0.33x12, 0.3x40,
0.4x12, 0.4x13, 0.4x16, 0.4x19, 0.4x20, 0.4x40,
0.45x12, 0.45x13, 0.45x16, 0.45x20, 0.45x25, 0.45x40,
0.5x16, 0.5x19, 0.5x20, 0.5x25, 0.5x42, 0.5x60,
0.55x25, 0.55x38, 0.55x40,
0.6x16, 0.6x25, 0.6x30, 0.6x40, 0.6x60,
0.7x30, 0.7x35, 0.7x40, 0.7x50, 0.7x90,
0.8x16, 0.8x25, 0.8x30, 0.8x38, 0.8x40, 0.8x50, 0.8x70, 0.8x100,
0.9x25, 0.9x38, 0.9x40, 0.9x50, 0.9x70,
1.1x25, 1.1x30, 1.1x38, 1.1x40, 1.1x50,
1.2x25, 1.2x30, 1.2x38, 1.2x40, 1.2x50, 1.2x65, 1.2x70, 1.2x100,
1.5x50, 1.5x100,
1.6x15, 1.6x25, 1.6x35, 1.6x40, 1.6x70, 1.6x110,
1.8x40, 1.8x50, 1.8x65, 1.8x70, 1.8x100, 1.8x110,
2.0x30, 2.0x40, 2.0x50, 2.0x65, 2.0x70, 2.0x100, 2.0x110, 2.0x120,
2.1x40, 2.1x50, 2.1x120

c) Filter



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Katarína Tomin Srdošová, PhD.
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Valid until 30.09.2027

# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use | CHIRANA | 1ml 27G x 1/2"U100 | CHINS0127 |
| | | 1ml 29G x 1/2"U40 | CHINS4129 |
| | | 1ml 29G x 5/16"U100 | CHINS01298 |
| | | 1ml 29G x 1/2"U100 | CHINS0129 |
| | | 1ml 30G x 1/2"U100 | CHINS0130 |
| | | 1ml 30G x 5/16"U100 | CHINS01308 |
| | | 1ml 31G x 4/16"U100 | CHINS01316 |
| | | 1ml 31G x 5/16"U100 | CHINS01318 |
| | | 1 ml Luer – U100 | CHINS01 |
| | | 1ml Luer – U40 | CHINS41 |
| | | 0,5ml 29G x 1/2"U100 | CHINS00529 |
| | | 0,5ml 30G x 1/2"U100 | CHINS00530 |
| | | 0,5ml 30G x 5/16"U100 | CHINS005308 |
| | | 0,5ml 31G x 5/16"U100 | CHINS005318 |
| | | 0,5ml 31G x 4/16"U100 | CHINS005316 |
| | | 0,3ml 29G x 1/2"U100 | CHINS00329 |
| | | 0,3ml 30G x 1/2"U100 | CHINS00330 |
| | | 0,3ml 30G x 5/16"U100 | CHINS003308 |
| | | 0,3ml 31G x 5/16"U100 | CHINS003318 |
| | | 0,3ml 31G x 4/16"U100 | CHINS003316 |
| | | 1ml 27G x 1/2"U100 | CHINS0127PB |
| | | 1ml 29G x 1/2"U40 | CHINS4129PB |
| | | 1ml 29G x 5/16"U100 | CHINS01298PB |
| | | 1ml 29G x 1/2"U100 | CHINS0129PB |
| | | 1ml 30G x 1/2"U100 | CHINS0130PB |
| | | 1ml 30G x 5/16"U100 | CHINS01308PB |
| | | 1ml 31G x 4/16"U100 | CHINS01316PB |



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# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-026

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## 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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use | CHIRANA | 1ml 31G x 5/16"U100<br>0,5ml 29G x 1/2"U100<br>0,5ml 30G x 1/2"U100<br>0,5ml 30G x 5/16"U100<br>0,5ml 31G x 5/16"U100<br>0,5ml 31G x 4/16"U100<br>0,3ml 29G x 1/2"U100<br>0,3ml 30G x 1/2"U100<br>0,3ml 31G x 5/16"U100<br>0,3ml 31G x 4/16"U100 | CHINS01318PB<br>CHINS00529PB<br>CHINS00530PB<br>CHINS005308PB<br>CHINS005318PB<br>CHINS005316PB<br>CHINS00329PB<br>CHINS00330PB<br>CHINS003318PB<br>CHINS003316PB |
| Sterile Tubercilin Syringe with / without Integrated Needle or Side Packed Needle for Single Use | CHIRANA | 1 ml Luer<br>1ml 29G x 1/2" | CHTUB01<br>CHTUB0129 |



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## 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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use | HARMOFINE | 1ml 27G x 1/2"U100 | HFINS0127 |
| | | 1ml 29G x 1/2"U40 | HFINS4129 |
| | | 1ml 29G x 5/16"U100 | HFINS01298 |
| | | 1ml 29G x 1/2"U100 | HFINS0129 |
| | | 1ml 30G x 1/2"U100 | HFINS0130 |
| | | 1ml 30G x 5/16"U100 | HFINS01308 |
| | | 1ml 31G x 4/16"U100 | HFINS01316 |
| | | 1ml 31G x 5/16"U100 | HFINS01318 |
| | | 1 ml Luer – U100 | HFINS01 |
| | | 1ml Luer – U40 | HFINS41 |
| | | 0,5ml 29G x 1/2"U100 | HFINS00529 |
| | | 0,5ml 30G x 1/2"U100 | HFINS00530 |
| | | 0,5ml 30G x 5/16"U100 | HFINS005308 |
| | | 0,5ml 31G x 5/16"U100 | HFINS005318 |
| | | 0,5ml 31G x 4/16"U100 | HFINS005316 |
| | | 0,3ml 29G x 1/2"U100 | HFINS00329 |
| | | 0,3ml 30G x 1/2"U100 | HFINS00330 |
| | | 0,3ml 30G x 5/16"U100 | HFINS003308 |
| | | 0,3ml 31G x 5/16"U100 | HFINS003318 |
| | | 0,3ml 31G x 4/16"U100 | HFINS003316 |
| | | 1ml 27G x 1/2"U100 | HFINS0127PB |
| | | 1ml 29G x 1/2"U40 | HFINS4129PB |
| | | 1ml 29G x 5/16"U100 | HFINS01298PB |
| | | 1ml 29G x 1/2"U100 | HFINS0129PB |
| | | 1ml 30G x 1/2"U100 | HFINS0130PB |
| | | 1ml 30G x 5/16"U100 | HFINS01308PB |
| | | 1ml 31G x 4/16"U100 | HFINS01316PB |



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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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| **Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use** | **HARMOFINE** | 1ml 31G x 5/16"U100<br>0,5ml 29G x 1/2"U100<br>0,5ml 30G x 1/2"U100<br>0,5ml 30G x 5/16"U100<br>0,5ml 31G x 5/16"U100<br>0,5ml 31G x 4/16"U100<br>0,3ml 29G x 1/2"U100<br>0,3ml 30G x 1/2"U100<br>0,3ml 31G x 5/16"U100<br>0,3ml 31G x 4/16"U100 | HFINS01318PB<br>HFINS00529PB<br>HFINS00530PB<br>HFINS005308PB<br>HFINS005318PB<br>HFINS005316PB<br>HFINS00329PB<br>HFINS00330PB<br>HFINS003318PB<br>HFINS003316PB |
| **Sterile Tuberculin Syringe with / without Integrated Needle or Side Packed Needle for Single Use** | **ACTI-FINE** | 1 ml Luer | S381CE0T1 |

**Versions:**

Insulin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G - U40/U100
1 ml Luer - U100

Tuberculin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G

1 ml Luer

- blister / polybag



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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-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Perfusion Syringe for Single Use | CHIRANA | 20ml - Perfusion syringe Luer-Lock transparent with red stopper | CH03020PT |
| | | 30ml - Perfusion syringe Luer-Lock transparent with red stopper | CH03030PT |
| | | 50ml - Perfusion syringe Luer-Lock transparent | CH03050PT |
| | | 50ml - Perfusion syringe Luer-Lock, BB transparent | CH03050PTB |
| | | 50ml - Perfusion syringe Luer-Lock, F transparent | CH03050PTF |
| | | 50ml - Perfusion syringe Luer-Lock, F transparent with red stopper | CH03050PTFS |
| | | 50ml - Perfusion syringe Luer-Lock transparent with needle 2,0x30mm | CH030502030PT |
| | | 50ml - Perfusion syringe Luer-Lock, BB transparent with needle 2,0x30mm | CH030502030PTB |
| | | 50ml - Perfusion syringe Luer-Lock, F transparent with needle 1,8x40mm | CH030501840PTF |
| | | 50ml - Perfusion syringe Luer-Lock opaque | CH03050PO |
| | | 50ml - Perfusion syringe Luer-Lock, BB opaque | CH03050POB |
| | | 50ml - Perfusion syringe Luer-Lock, F opaque | CH03050POF |
| | | 50ml - Perfusion syringe Luer-Lock opaque with needle 2,0x30mm | CH030502030PO |
| | | 50ml - Perfusion syringe Luer-Lock, BB opaque with needle 2,0x30mm | CH030502030POB |
| | | 50ml - Perfusion syringe Luer-Lock, F opaque with needle 1,8x40mm | CH030501840POF |
| | | 50ml - Perfusion syringe Luer-Lock, F opaque with needle 2,0x30mm | CH030502030POF |
| | | 50ml – Perfusion syringe Luer-Lock, BB black | CH03050PBB |
| | | 50ml - Perfusion syringe Luer-Lock, BB black with needle 2,0x30mm | CH030502030PBB |



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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-026

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:**

| Product | Trade Name | Models | REF code |
|---|---|---|---|
| Sterile Perfusion Syringe for Single Use | INFUJECT/ PERFUJECT | 20ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT | 21021 |
| | | 30ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT | 22030 |
| | | 50ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT | 22050 |
| | | 50ml – syringe for infusion pumps Luer-Lock transparent (Kanüle:2,0x30) – INFUJECT | 22054 |
| | | 50ml – syringe for infusion pumps Luer-Lock amber (Kanüle:2,0x30) – INFUJECT | 22064 |
| | | 50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent – PERFUJECT | 22051 |
| | | 50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent (Kanüle:2,0x30) – PERFUJECT | 22052 |
| | | 50ml – syringe for infusion pumps Luer-Lock "Typ P" amber (Kanüle:2,0x30) – PERFUJECT | 22063 |
| | | 50ml – syringe for infusion pumps Luer-Lock "Typ P" black (Kanüle:2,0x30) – PERFUJECT | 22053 |



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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-026

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:**

Sterile Hypodermic Syringe for Single Use: CHIRANA / ECOJECT - injection and taking off a blood and other liquids at patients

Sterile Injection Set for Single Use: CHIRANA / SYRISET - injection and taking off a blood and other liquids at patients

Sterile Insulin / Tuberculin Syringe With / Without Integrated Needle or Side Packed Needle for single Use: CHIRANA / ACTI-FINE / HARMOFINE – Insulin syringe - administration of 1 ml; 0,5 ml or 0,3 ml; that is 100, 50 or 30 units of U 100 insulin, or 1ml of 40 units of U 40 insulin. Tuberculin syringe - administration of vaccines immediately after filling, not to store vaccines for prolonged period of time

Sterile Perfusion Syringe for Single use: CHIRANA / INFUJECT / PERFUJECT - drug application into human body via syringe pumps. Needle is for piercing the vials and bags and taking the drug into the syringe. Attached stopper is for temporarily closure of the syringe with prepared drug. Syringe opaque / black is for using with light sensitive drugs and solutions. Syringes can also be used for withdrawing fluids from human body or for administration of fluids into the human body.



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-026

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-026 | 30.09.2022 | MDR096_2022, MDR098_2022, MDR099_2022, MDR103_2022 | Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR. |



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

# EU Declaration of Conformity

RF-007517-k

**Legal Manufacturer:** SenTec AG
Ringstrasse 39, CH-4106 Therwil, Switzerland
Phone +41 61726 97 60

**SRN:** Not yet available

**EU Authorized Representative:** SenTec GmbH, Carl-Hopp-Strasse 19A, 18069 Rostock, Germany
Phone +49(0)381 367796 120

This declaration of conformity is issued under the sole responsibility of SenTec AG.

**Accessories and Disposables for the SenTec Digital Monitoring System (SDMS)**
Accessories and disposables to be used with the SDMS for non-invasive monitoring of vital parameters.

| Product Name | REF | Basic UDI-DI | Intended Purpose |
|---|---|---|---|
| Digital Sensor Adapter Cable | AC-XXX | 764012188ACRM | AC-XXX is required to connect digital SenTec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the SenTec Digital Monitor. |
| Ear Clip | EC-MI | 764012188ECRZ | SenTec's Ear Clip, model EC-MI, is intended for use with the V-Sign™ Sensor 2 when continuous, noninvasive tcPCO2, SpO2, and PR monitoring are required, and with the OxiVenT™ Sensor when continuous, noninvasive tcPCO2 and tcPO2 monitoring as well as SpO2 and PR monitoring are required. The Ear Clip is indicated to attach the V-Sign™ Sensor 2 or OxiVenT™ Sensor to the earlobe of the patient. |
| Multi-Site Attachment Ring for mature/intact skin | MAR-MI and MARe-MI | 764012188MARJD | SenTec's Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach V-Sign™ Sensor 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, noninvasive tcPCO2 monitoring is required for adult, pediatric, and neonatal patients. The Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach the OxiVenT™ Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, noninvasive tcPCO2 and/or tcPO2 monitoring is required for adult, pediatric, and neonatal patients. If SpO2 and PR monitoring are (additionally) required for adult and pediatric patients, the Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach the V-Sign™ Sensor 2 or the OxiVenT™ Sensor to the forehead, cheek, upper arm as well as on the shoulder blade. |

| | | | |
|---|---|---|---|
| Multi-Site Attachment Ring for sensitive/fragile skin | MAR-SF and MARe-SF | 764012188MARJD | SenTec's Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach V-Sign™ Sensor 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, noninvasive tcPCO2 monitoring is required for adult, pediatric, and neonatal patients. The Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach the OxiVenT™ Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, noninvasive tcPCO2 and/or tcPO2 monitoring is required for adult, pediatric, and neonatal patients. If SpO2 and PR monitoring are (additionally) required for adult and pediatric patients, the Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach the V-Sign™ Sensor 2 or the OxiVenT™ Sensor to the forehead, cheek, upper arm as well as on the shoulder blade. |
| Staysite™ Adhesive for Multi-Site Attachment Rings | SA-MAR | 764012188SA-MAR6E | SenTec's Staysite™ Adhesive for MAR, model SA-MAR, is an optional, single-use adhesive which is indicated for use with Multi-Site Attachment Rings, models MAR-MI, MARe-MI, MAR-SF, and MARe-SF, if more secure attachment is required. |
| Membrane Changer | MC<br>MC-R | 764012188MCSR | The Membrane Changer single-use (MC), the Membrane Changer reloadable (MC-R), and the Membrane Changer Insert (MC-I), serve as tools to change the electrolyte and membrane of SenTec transcutaneous sensors. The Membrane Changer reloadable (MC-R) can be reused by replacing its insert (MC-I). |
| Membrane Changer Insert | MC-I | 764012188MCSR | |
| Service Gas | GAS-0812 | 764012188GAS-08127M | The Service Gas, model GAS-0812, serves as calibration gas for the SenTec transcutaneous sensors that monitor tcPCO2 and/or tcPO2 (V-Sign™ Sensor 2 and OxiVenT™ Sensor). |
| Contact Gel | GEL-04<br>GEL-SD | 764012188GELHF | The Contact Gel, GEL-04 and GEL-SD, serves as contact gel to achieve proper gas conduction and heat transfer between the patient's skin and the SenTec transcutaneous sensors. Contact Gel makes direct patient contact (intact skin, prolonged exposure <30 days). |
| PSG Adapter Cable | PSG Cable A to PSG Cable X | 764012188PSGKU | PSG Cables are intended to interface the SenTec Digital Monitor to Polygraphs (PG) or Polysomnographs (PSG). |
| Isolation Transformer | RFT100VA-XX | 764012188RFTKR | Isolation Transformers are intended ensure a galvanic separation of the SenTec Digital Monitor from supply voltage in home care installation settings. |
| SDM Water protection cover | SDM_WPC | 764012188WPCLE | SDM_WPC is intended to protect the SenTec Digital Monitor from water ingress to meet the IPX2 requirements. |

**Classification:** Class I, according to Rule 1, Annex VIII, MDR EU 2017/745.

We hereby declare that the products specified above meet all provision of the Regulation (EU) MDR 2017/745 for medical devices which apply to them.

We hereby declare that the products specified above meet all provisions of the Directive 2011/65/EU (RoHS) which apply to them.

We hereby declare that the products specified above meet all provisions of the Regulation (EU) 2016/679 (GDPR) which apply to them.

The products specified above comply with the general safety and performance requirements of MDR 2017/745 Annex I and all applicable harmonized standards.

**Notified Body:** TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
NB 0123

This declaration is supported by the Quality System approval to EN ISO 13485:2016 issued by TÜV SÜD Product Service GmbH, Germany.

Therwil, January 22nd, 2021 On behalf of SenTec AG

.....

Dominik Ellenrieder

Chairman of the Executive Board

Caroline Möller, Ph.D.

Head of Regulatory Affairs & Quality Assurance

sentec

# EU Declaration of Conformity

**RF-005387-v**

| | |
|---|---|
| **Legal Manufacturer:** | Sentec AG,<br>Ringstrasse 39, CH-4106 Therwil, Switzerland |
| **SRN Manufacturer:** | CH-MF-000008058 |
| **EU Authorized Representative:** | Sentec GmbH<br>Carl-Hopp-Strasse 19A, DE-18069 Rostock, Germany |
| **SRN Representative:** | DE-AR-000007618 |

This declaration of conformity is issued under the sole responsibility of Sentec AG.

**Accessories and Disposables for the Sentec Digital Monitoring System (SDMS)**
Accessories and disposables to be used with the SDMS for non-invasive monitoring of vital parameters.

| Product Name | REF | Basic UDI-DI | Intended Purpose |
|---|---|---|---|
| Sentec Digital Monitor | SDM | 764012188SDMKA | The Sentec Digital Monitor, model SDM, is a portable stand-alone patient monitor indicated for continuous, noninvasive patient monitoring of carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), functional oxygen saturation (SpO2) and pulse rate (PR), using either<br>• a single, digital sensor (V-Sign™ Sensor 2) for PCO2, SpO2 and PR measurement, OR<br>• a single, digital sensor (OxiVenT™ Sensor) for PCO2, PO2, SpO2 and PR measurement.<br><br>PO2 measurement with SDM is only possible when used in combination with an OxiVenT™ Sensor. |
| V-Sign™ Sensor 2 | VS-A/P/N | 764012188VSUL | The V-Sign™ Sensor 2, model VS-A/P/N, is indicated for use with the SDM when continuous, noninvasive monitoring of tcPCO2, SpO2, and PR are required for adult and pediatric patients. In neonatal patients, the use of V-Sign™ Sensor 2 is indicated for tcPCO2 monitoring only. |
| OxiVenT™ Sensor | OV-A/P/N | 764012188OVU5 | The OxiVenT™ Sensor, model OV-A/P/N, is indicated for use with the SDM when continuous, noninvasive monitoring of tcPCO2, and tcPO2, as well as SpO2, and PR monitoring are required for adult and pediatric patients. In neonatal patients, the use of OxiVenT™ Sensor is indicated for tcPCO2 and tcPO2 monitoring only. tcPO2 monitoring is contraindicated for patients under gas anesthesia. |

Classification: Class IIb, according to Rule 10, annex VIII, MDR 2017/745.

We hereby declare that the products specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

We hereby declare that the products specified above meet all provisions of the Directive 2011/65/EU (RoHS) which apply to them.

We hereby declare under our sole responsibility that the products specified above meet all provisions of the Regulation (EU) 2016/679 (GDPR) which apply to them.

The products specified above comply with the general safety and performance requirements of MDR 2017/745 Annex I and all applicable harmonized standards.

sentec.

| | |
|---|---|
| Notified Body: | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65, 80339 Munich, Germany<br>NB number 0123 |
| Certification number: | G10 005260 0004 Rev. 00 |

The products are subject of the procedure set out in MDR 2017/745 Annex IX Chapters I and III under the supervision of TÜV SÜD Product Service GmbH.

This declaration is supported by the Quality System approval to EN ISO 13485 issued by TÜV SÜD Product Service GmbH.

Therwil, September 9, 2021

On behalf of Sentec AG

i. V.

Dominik Ellenrieder

President Sentec AG

Caroline Möller, Ph.D.

Head of Regulatory Affairs & Quality Assurance

# ES atitikties deklaracija

RF-007517-k

| | |
|---|---|
| **Teisėtas gamintojas:** | SenTec AG<br>Ringstrasse 39, CH-4106 Therwil, Šveicarija<br>Telefonas +41 61726 97 60 |
| **SRN:** | Dar nepasiekiama |
| **ES įgaliotasis atstovas:** | SenTec GmbH, Carl-Hopp-Strasse 19A, 18069 Rostokas, Vokietija<br>Telefonas +49(0)381 367796 120 |

Ši atitikties deklaracija išduota tik "SenTec AG" atsakomybe.

**"SenTec" skaitmeninės stebėjimo sistemos (SDMS) priedai ir vienkartiniai reikmenys**

Priedai ir vienkartiniai reikmenys, naudojami kartu su SDMS neinvaziniam gyvybinių parametrų stebėjimui.

| Produkto pavadinimas | NUORODA | Bazinis UDI-DI | Numatyta paskirtis |
|---|---|---|---|
| Skaitmeninio jutiklio adapterio kabelis | AC-XXX | 764012188ACRM | AC-XXX reikalingas norint prijungti skaitmeninius SenTec jutiklius (V-Sign™ Sensor 2, OxiVenT™ Sensor) prie SenTec monitoriaus. |
| Ausies spaustukas | EB-MI | 764012188ECRZ | "SenTec" ausų spaustukas, modelis EC-MI, skirtas naudoti su "V-Sign™ Sensor 2", kai reikalingas nuolatinis, neinvazinis tcPCO2, SpO2 ir PR stebėjimas, ir su "OxiVenT™" jutikliu, kai reikalingas nuolatinis, neinvazinis tcPCO2 ir tcPO2 stebėjimas, taip pat SpO2 ir PR stebėjimas. Ausies spaustukas skirtas pritvirtinti "V-Sign™ Sensor 2" arba "OxiVenT™" jutiklį prie paciento ausies spenelio. |
| Kelių vietų tvirtinimo žiedas brandžiai / nepažeistai odai | MAR-MI ir MARe-MI | 764012188MARJD | "SenTec" kelių vietų tvirtinimo žiedai, modeliai MAR-MI ir MARe-MI, skirti pritvirtinti V ženklo™ jutiklį 2 prie įprastų matavimo vietų anglies dioksido įtempimo stebėjimui, kai suaugusiems, vaikams ir naujagimiams reikalingas nuolatinis, neinvazinis tcPCO2 stebėjimas. Kelių vietų tvirtinimo žiedai, modeliai MAR-MI ir MARe-MI, yra skirti prijungti "OxiVenT™" jutiklį prie įprastų matavimo vietų anglies dioksido ir (arba) deguonies įtempimo stebėjimui, kai suaugusiems, vaikams ir naujagimiams reikalingas nuolatinis, neinvazinis tcPCO2 ir (arba) tcPO2 stebėjimas. Jei suaugusiems ir vaikams reikalingas SpO2 ir PR stebėjimas, " Multi-Sites" tvirtinimo žiedai, modeliai MAR-MI ir MARe-MI, skirti pritvirtinti "V-Sign™ Sensor 2" arba "OxiVenT™" jutiklį prie kaktos, skruosto, žasto ir pečių. |

| | | | |
|---|---|---|---|
| Kelių vietų tvirtinimo žiedas jautriai / trapiai odai | MAR-SF ir MARe-SF | 764012188MARJD | "SenTec" kelių vietų tvirtinimo žiedai, modeliai MAR-SF ir MARe-SF, skirti pritvirtinti V ženklo™ jutiklį 2 prie įprastų matavimo vietų anglies dioksido įtempimo stebėjimui, kai suaugusiems, vaikams ir naujagimiams reikalingas nuolatinis, neinvazinis tcPCO2 stebėjimas. Kelių vietų tvirtinimo žiedai, modeliai MAR-SF ir MARe-SF, yra skirti prijungti "OxiVenT™" jutiklį prie įprastų anglies dioksido ir (arba) deguonies įtempimo stebėjimo vietų, kai suaugusiems, vaikams ir naujagimiams reikalingas nuolatinis, neinvazinis tcPCO2 ir (arba) tcPO2 stebėjimas. Jei suaugusiems ir vaikams reikalingas SpO2 ir PR stebėjimas ( papildomai), kelių vietų tvirtinimo žiedai, modeliai MAR-SF ir MARe-SF, skirti pritvirtinti V ženklo ™ jutiklį 2 arba "OxiVenT™" jutiklį prie kaktos, skruosto, žasto ir pečių. |
| "Staysite™ " lipdukas skirtas kelių vietų tvirtinimo žiedams | SA-MAR | 764012188SA-MAR6E | "SenTec" "Staysite™ Adhesive for MAR", modelis SA-MAR, yra pasirenkami vienkartiniai klijai, skirti naudoti su kelių vietų tvirtinimo žiedais, modeliais MAR-MI, MARe-MI, MAR-SF ir MARe-SF, jei reikia saugesnio tvirtinimo. |
| Membrano s keitiklis | MC<br>MC-R | 764012188MCSR | Vienkartinis membranos keitiklis (MC), pakartotinai įkraunamas membranos keitiklis (MC-R) ir membranos keitiklio įdėklas (MC-I) yra įrankiai, skirti pakeisti "SenTec" transkutaninių jutiklių elektrolitą ir membraną. Pakartotinai įkraunamą membranos keitiklį (MC-R) galima pakartotinai naudoti pakeičiant jo įdėklą (MC-I). |
| Membranos keitiklio įdėklas | MC-I | 764012188MCSR | |
| Aptarnavimo dujos | GAS-0812 | 764012188GAS-08127M | "Service Gas", modelis GAS-0812, tarnauja kaip kalibravimo dujos " SenTec" transkutaniniams jutikliams, kurie stebi tcPCO2 ir (arba) tcPO2 ("V-Sign™ Sensor 2" ir "OxiVenT" jutiklis™). |
| Kontaktinis gelis | GEL-04<br>GEL-SD | 764012188GELIOHF | Kontaktinis gelis, GEL-04 ir GEL-SD, tarnauja kaip kontaktinis gelis, kad būtų pasiektas tinkamas dujų laidumas ir šilumos perdavimas tarp paciento odos ir "SenTec" transkutaninių jutiklių. Contact Gel sukelia tiesioginį kontaktą su pacientu (nepažeista oda, ilgalaikis poveikis <30 dienų). |
| PSG adapterio kabelis | PSG kabelis nuo A iki PSG kabelis X | 764012188PSGKU | PSG kabeliai skirti susieti "SenTec" skaitmeninį monitorių su poligrafais ( PG) arba polisomnografais (PSG). |
| Izoliacijos transformat orius | RFT100VA-XX | 764012188RFTKR | Izoliaciniai transformatoriai skirti užtikrinti galvaninį "SenTec" skaitmeninio monitoriaus atskyrimą nuo maitinimo įtampos namų priežiūros įrengimo vietose. |
| SDM Vandens apsaugos dangtelis | SDM_WPC | 764012188WPCLE | SDM_WPC skirtas apsaugoti "SenTec" skaitmeninį monitorių nuo vandens patekimo, kad atitiktų IPX2 reikalavimus. |

**Klasifikacija:** Klasė I, pagal Taisyklę 1, priedą VIII, MDR ES 2017/745.

Mes patvirtiname, kad aukščiau išvardyti produktai atitinka visas Reguliacijos (ES) MDR 2017/745 sąlygas medicininiams prietaisams, kurios jiems taikomos.
Mes patvirtiname, kad aukščiau išvardyti produktai atitinka visas Direktyvos 2011/65/ES (RoHS) sąlygas, kurios jiems taikomos.
Mes patvirtiname, kad aukščiau išvardyti produktai atitinka visas Reguliacijos (ES) 2016/679 (GDPR) sąlygas, kurios jiems taikomos.
Aukščiau išvardyti produktai atitinka bendrus saugos ir veikimo reikalavimus pagal MDR 2017/745 prieadą I ir visus taikomus harmonizuotus standartus.

**Notifikuotoji įstaiga:** TUV SUD Product Service GmbH
Ridlerstasse 65, 80339 Miunchenas, Vokietija
NB 0123

Ši deklaracija paremta Kokybės Sistemos patvirtinimu pagal EN ISO 1385:2016 išduotu pagal TUV SUD Product Service GmbH, Vokietija.

Therwil, Sausio 22d., 2021 SenTec AG vardu

(parašas)
Dominik Ellenrieder
Pirmininkas

(parašas)
Caroline Moller, Ph.D.
Reguliavimo reikalų ir kokybės užtikrinimo vadovė

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 038814 0086 Rev. 00**

**Manufacturer:**

**Well Lead Medical Co., Ltd.**
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):** **Urethral Catheter，Connecting Tube with or without Yankauer Handle, Silicone Stomach Tube, Nelaton Catheter, Silicone Tube, Suction ToothBrush, Capnography CO2 Sampling Mask, O2+CO2 Sampling Cannula, Bile T-Tube, Intermittent Catheter, Tracheal Tube, Endotracheal Tube Kit, Reinforced Endotracheal Tube, Endotracheal Tube with Evacuation Lumen, Laryngeal Mask Device, Intubating Stylet, Endotracheal Tube Introducer, Endobronchial Tube, Endobronchial Blocker Tube**

tubes

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.:** SH19080CN01

**Valid from:** 2020-03-31

**Valid until:** 2024-05-26

**Date,** 2020-03-31

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

# CE SERTIFIKATAS

## Pilna kokybės užtikrinimo sistema

**Medicinos prietaisų direktyva 93/42/EEB (MDD), Priedas II išskyrus (4)**
**(IIa, IIb ar III klasės prietaisai)**

## Nr. G1 038814 0086 perž. 00

**Gamintojas:** **Well Lead Medical Co., Ltd.**
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
KINIJOS LIAUDIES RESPUBLIKA

**Produkto kategorija(os): Ureteriniai kateteriai, prailginimo vamzdeliai arba Yankauer laikikliai, silikoniai skrandžio vamzdeliai, Nelatoniniai kateteriai, Silikoniniai vamzdeliai, dantų šepetėliai su atsiurbimu, CO2 matavimo kaukės, O2+CO2 matavimo kaniulės, tracheostominiai vamzdeliai, endotrachėjiniai vamzdeliai, armuoti endotrachėjiniai vamzdeliai, endotrachėjinia vamzdeliai su atsiurbimu, laringinės kaukės, intubavimo stiletas, endotrachėjinio vamzdelio įvedėjas, endotronchiniai vamzdeliai, endobronchiniai vamzdeliai-blokatoriai.**

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 93/42/EEB II Priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. III klasės produktams yra privalomas papildomas II (4) priedo sertifikatas. Taip pat žr. kitame lape.

**Protokolo Nr.** SH19080CN01

**Galioja nuo:** 2020-03-31
**Galioja iki:** 2024-05-26

**Data**, 2020-03-31 /parašas/
Christoph Dicks
Sertifikavimo / notifikuotosios įstaigos vadovas



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

TÜV SÜD Product Service GmbH * Sertifikavimo įstaiga * Ridlerstrasse 65 * 80339* Miunchenas * Vokietija

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**

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

**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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

**Notified Body**

**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**

**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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Bo[illegible]

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 E

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**

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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**

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**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**

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# LGA Products GmbH
# Tillystrasse 2, 90431 Nürnberg

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**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 įs**

/parašas/ /ar
**Rafal Byczko**

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