



C E R T I F I C A T E

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

M.2016.106.6908-1 Design Examination Certificate Was Prepared for Class III Products Defined In This Certificate.

Company Name : TMT Tibbi Medikal Matzemeleri San. ve Tic. Ltd. Şti.

Company Address : Fatih Mah. 1188 Sok. No: 14 Sarnıç Gazıemir IZMIR / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II
(Excluding Section 4)

Product : 1- Spinal Anesthesia Needles – Sets – Kits – Class III – Sterile
- Spinal Anesthesia Needles
- Spinal Anesthesia Sets
- Spinal Epidural Combined Anesthesia Sets
- Spinal Epidural Combined Anesthesia Kits
2- Epidural Anesthesia Needles – Sets – Kits – Class IIa – Sterile
- Epidural Anesthesia Needles
- Epidural Anesthesia Sets
- Epidural Anesthesia Kits
- Caudal Anesthesia Needles
3- Intrauterine Contraceptive Device – Class III – Sterile
4- Seldinger (Angiography) Needle – Class III - Sterile
5- Biopsy and Aspiration Needles and Accessories – Class IIa - Sterile
6- Medical Accessories for Infusion – Class I - Sterile

Product Types are attached.

Certificate Number : M.2016.106.6908
Report Number : MD.3193.IB
Initial Assessment Date : 16.07.2016
Registration Date : 28.07.2016
Revision Date /No : -
Expiry Date : 27.07.2021

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 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 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 II devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon 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 the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemitd.com.tr.

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@udemitd.com.tr www.udemitd.com.tr

CE
2292



Višeju pismu specijaliste
Greta Rumsvidare



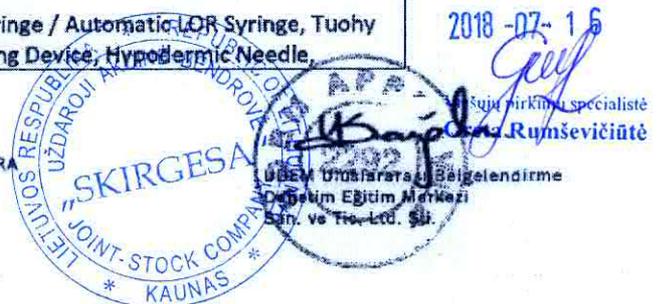
This document containing 2 (two) pages is the Annex of the Certificate with the number M.2016.106.6908 and with the registration date of 28.07.2016 issued for "TMT Tibbi Medikal Malzemeleri San. ve Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Spinal Anesthesia Needles – Sets – Kits – Class III – Sterile
Spinal Anesthesia Needles
Quincke Type Spinal Anesthesia Needles
Atraumatic Type (Pencil) Spinal Anesthesia Needles
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles
Spinal Anesthesia Sets
Spinal Anesthesia Sets with Quincke Type Spinal Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, Syringe 5ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress / Gauze Ball, Forceps)
Spinal Anesthesia Sets with Atraumatic Type (Pencil Point) Spinal Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, Syringe 5ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress / Gauze Ball, Forceps)
Spinal Anesthesia Sets with Specially Grinded – Curved Type Atraumatic Spinal Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, Syringe 5ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress / Gauze Ball, Forceps)
Spinal Epidural Combined Anesthesia Sets
Spinal Epidural Combined Anesthesia Sets: (Epidural Needle with Combined Application Fixator, Spinal Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Tuohy Borst Connector, Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Filtered Aspiration Cannula)
Spinal Epidural Combined Anesthesia Sets – Single Shot Spinal Epidural Combined Anesthesia Application Sets: (Epidural Needle with Combined Application Fixator, Spinal Needle, Epidural LOR Syringe / Automatic LOR Syringe, Filtered Aspiration Cannula)
Spinal Epidural Combined Anesthesia Kits
Spinal Epidural Combined Anesthesia Kits: (Epidural Needle with Combined Application Fixator, Spinal Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Tuohy Borst Connector, Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Filtered Aspiration Cannula, Hypodermic Needle, Syringe 5ml/2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Sticking Plaster, Sponge)
Spinal Epidural Combined Anesthesia Kits - Single Shot Spinal Epidural Combined Anesthesia Application Kits: (Epidural Needle with Combined Application Fixator, Spinal Needle, Epidural LOR Syringe / Automatic LOR Syringe, Filtered Aspiration Cannula, Hypodermic Needle, Syringe 5ml/2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Sponge)
Epidural Anesthesia Needles – Sets – Kits – Class IIa – Sterile
Epidural Anesthesia Needles
Epidural Anesthesia Sets
Epidural Anesthesia Sets: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Tuohy Borst Connector, Epidural Catheter Fixing Device, Epidural Filter Fixing Device)
Epidural Anesthesia Sets (Mini A): (Epidural Needle, Epidural Catheter, Epidural Filter, Tuohy Borst Connector)
Epidural Anesthesia Sets (Mini B): (Epidural Catheter, Epidural Filter, Tuohy Borst Connector)
Epidural Anesthesia Sets (Mini C): (Epidural Needle, Epidural Catheter, Tuohy Borst Connector)
Epidural Anesthesia Kits
Epidural Anesthesia Kits: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Tuohy Borst Connector, Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Hypodermic Needle,

KOPIJA TIKRA

2018-07-16

Svejkirktis specialiste
Rumševičiūtė





This document containing 2 (two) pages is the Annex of the Certificate with the number M.2016.106.6908 and with the registration date of 28.07.2016 issued for "TMT Tibbi Medikal Malzemeleri San. ve Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Syringe 5ml / 2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Plaster, Sponge)
Epidural Anesthesia Kits (Mini A): (Epidural Needle, Epidural Catheter, Epidural Filter, Tuohy Borst Connector, Hypodermic Needle, Syringe 5ml/2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Plaster, Sponge)
Epidural Anesthesia Kits (Mini B): (Epidural Catheter, Epidural Filter, Tuohy Borst Connector, Hypodermic Needle, Syringe 5ml/2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Plaster, Sponge)
Epidural Anesthesia Kits (Mini C) (Epidural Needle, Epidural Catheter, Tuohy Borst Connector, Hypodermic Needle, Syringe 5ml/2ml, Adhesive Surgical Drape, Surgical Towel, Medical Gauze Compress, Plaster, Sponge)
Caudal Anesthesia Needles
Intrauterine Contraceptive Device – Class III – Sterile
Seldinger (Angiography) Needle – Class III – Sterile
Biopsy and Aspiration Needles and Accessories – Class IIa – Sterile
Manual Guillotine Biopsy Needle
Semi-Automatic Guillotine Biopsy Needle
Bone Marrow Biopsy Needle
Sternal Crista Iliac Aspiration Needle
Chiba Needle
Amniocentesis Needle
Guide Needle
Epidural Filter
Epidural LOR (Loss Of Resistance) Syringe
Epidural Automatic LOR (Loss Of Resistance) Syringe
Medical Accessories for Infusion – Class I – Sterile
Epidural Catheter Fixing Device
Epidural Filter Fixing Device
Tuohy Borst Connector

KOPIJA TIKRA

2018-07-16





SERTIFIKATAS

Pilna kokybės užtikrinimo sistema

Medicinos priemonių direktyva 93/42/EEB, II priedas

M.2016.106.6908-1 kūrimo sertifikatas yra skirtas III klasės produktams, nurodytiems šiame sertifikate.

Įmonės pavadinimas : TMT Tibbi Medikal Malzemeleri San. Ve Tic. Ltd. Sti.

Įmonės adresas : Faith Mah. 1188 Sok. Nr. 14 Sarnic Gaziemir
IZMIR/TURKIJA

Susijusios direktyvos ir priedai : MDD 93/42/EEB Medicinos priemonių direktyva – II priedas (išskyrus 4 skyrių)

Produktai : 1 – spinalinės anestezijos adatos – rinkiniai – komplektai – III klasė – sterilu
- spinalinės anestezijos adatos
- spinalinės anestezijos rinkiniai
- spinaliniai epidūriniai kombinuoti anestezijos rinkiniai
- spinaliniai epidūriniai kombinuoti anestezijos komplektai
: 2 – epidūrinės anestezijos adatos – rinkiniai – komplektai – IIa klasė – sterilu
- epidūrinės anestezijos adatos
- epidūrinės anestezijos rinkiniai
- epidūrinės anestezijos komplektai
- Kaudal tipo anestezijos adatos
: 3 – gimdos kontraceptinės priemonės – III klasė – sterilu
: 4 – Seldinger (angiografijos) adatos – III klasė – sterilu
: 5 – biopsijos ir aspiracijos adatos ir priedai – IIa klasė – sterilu
: 6 – medicininiai priedai infuzijai – I klasė – sterilu

Produktų tipai yra nurodyti priede.

Sertifikato numeris : M.2016.106.6908
Pranešimo numeris : MD.3193.IB
Pirminio įvertinimo data : 2016 07 16
Registracijos data : 2016 07 28
Peržiūrėjimo data/Nr : -
Galiojimo data : 2021 07 27



Šiuo dokumentu UDEM patvirtina, kad 93/42/EEB direktyvos II priedo, išskyrus 4 skyrių, reikalavimai tinka sąraše nurodytiems produktams. Aukščiau nurodytas gamintojas įdiegė ir taiko kokybės užtikrinimo sistemą, kuri periodiškai peržiūrima audito, pagal anščiau paminėtos direktyvos II priedo 5 skyrių. Remiantis II priedo 4 skyriumi, CE kūrimo-tyrimo sertifikatas yra reikalingas norint rinkoje parduoti III klasės priemones. Šis sertifikatas yra UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. nuosavybė, kuriai, šis sertifikatas turi būti grąžintas (pagal prašymą). Aukščiau nurodyta įmonė ir UDEM privalo saugoti šio sertifikato kopiją 5 metus nuo šio sertifikato įregistravimo. CE ženklo naudojimas yra priskiriamas gamintojo atsakomybei. Aukščiau paminėta įmonė privalo pranešti UDEM apie visus pakeitimus, susijusius su sąraše nurodytais produktais. Jeigu UDEM neatnaujins sertifikato galiojimo datos, aukščiau nurodyta įmonė turės sustabdyti produktų pardavinėjimą rinkoje. Sertifikato paplitimą galima pasitikrinti www.udemltd.com.fr internetiniame puslapyje.

Epidūrinės anestezijos rinkiniai (Mini B): (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, Tuohy tipo konektorius)
Epidūrinės anestezijos rinkiniai (Mini C): (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, Tuohy tipo konektorius)
Epidūrinės anestezijos komplektai
Epidūrinės anestezijos komplektai: (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, epidūrinis LOR švirkštas / automatinis LOR švirkštas, Tuohy tipo konektorius, epidūrinio kateterio fiksavimo priemonė, epidūrinio filtro fiksavimo priemonė, hipoderminė adata, švirkštas 5 ml / 2 ml, chirurginis paklotas, chirurginis rankšluostis, spaudžiamasis medicininis tvarstis, pleistras, kempinė)
Epidūrinės anestezijos komplektai (Mini A): (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, Tuohy tipo konektorius, hipoderminė adata, švirkštas 5 ml / 2 ml, chirurginis paklotas, chirurginis rankšluostis, spaudžiamasis medicininis tvarstis, pleistras, kempinė)
Epidūrinės anestezijos komplektai (Mini B): (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, Tuohy tipo konektorius, hipoderminė adata, švirkštas 5 ml / 2 ml, chirurginis paklotas, chirurginis rankšluostis, spaudžiamasis medicininis tvarstis, pleistras, kempinė)
Epidūrinės anestezijos komplektai (Mini C): (epidūrinė adata, epidūrinis kateteris, epidūrinis filtras, Tuohy tipo konektorius, hipoderminė adata, švirkštas 5 ml / 2 ml, chirurginis paklotas, chirurginis rankšluostis, spaudžiamasis medicininis tvarstis, pleistras, kempinė)
Kaudalinės anestezijos adatos
Gimdos kontraceptinės priemonės – III klasė – sterilu
Seldinger tipo (angiografijos) adata – III klasė - sterilu
Biopsijos ir aspiracijos adatos ir priedais – IIa klasė - sterilu
Mechaninė giljotinos tipo biopsijos adata
Pusiau automatinė giljotinos tipo biopsijos adata
Kaulų čiulpu biopsijos adata
Sternalinė aspiracinė adata
Chiba adata
Amniocentezės adata
Pravedimo adata
Epidūrinis filtras
Epidūrinis LOR švirkštas
Epidūrinis automatinis LOR švirkštas
Medicinos priedai infuzijai – I klasė – sterilu
Epidūrinio kateterio fiksavimo priemonė
Epidūrinio filtro fiksavimo priemonė
Tuohy tipo konektorius

KOPIJA TIKRA

2018-07-16



Greta Rumševičiūtė
 Greta Rumševičiūtė
 Gėsių birkių specialistė



EC Certificate Full Quality Assurance System: GB97/9239

The management system of

Flexicare Medical Ltd

Cynon Valley Business Park, Mountain Ash,
Mid Glamorgan, CF45 4ER, UK

has been assessed and certified as meeting the requirements of

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

For the following products

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

This certificate is valid from 18 April 2015 until 07 July 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 20 May 2017
Issue 26. Certified since 28 January 1997

Certification is based on reports numbered GB/PC 05884

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Page 1 of 2

KOPIJA TIKRA

018-07



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



Prešuju pirkinų specialistė
Greta Rumševičiūtė

Flexicare Medical Ltd

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

Issue 26

Detailed scope

Non-sterile: Breathing systems; humidification circuits; catheter mounts; oxygen therapy and aerosol masks; oxygen tubes; nebulisers; heat and moisture exchange (HME) filters; resuscitators for connection to active medical devices; carbon dioxide absorbent; Maxineb compressor; Dual Guard endoscopy bite block with O2 delivery and CO2 monitoring.

Sterile: endotracheal tubes; humidification chambers; breathing systems, Sterile single use and multiple use Laryngeal Mask Airways, Nasopharyngeal Airway (Nasosafe), Sterile single use Hall Lock spinal needle and spinal needle set, Sterile Silicone Foley catheters, Sterile latex Foley catheters. Sterile Bougie & Sterile Stylet, Sterile Suction catheter with side vacuum control. Sterile single use Suction Yankauers Sterile AeroCath drainage kit for nasal surgery Sterile breathing filters, sterile heat and moisture exchange (HME) filters.

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

KOPIJA TIKRA

Page 2 of 2

This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



CE sertifikatas, visiška kokybės užtikrinimo sistema: GB97/9239

valdymo sistema

FLECIXARE MEDICAL Ltd

Cynon Valley Business Park, Mountain Ash,
Mild Glamorgan, CF45ER, JK
nustatyta, kad atitinka

DIREKTYVOS 93/42/EEC

Dėl medicinos priemonių, II priedas (išskyrus 4 skyrių)

reikalavimus sekantiems produktams

Registravimo sritys nurodytos šio sertifikato antrame puslapyje.

Šis sertifikatas galioja nuo 2015 m. balandžio 18 d. iki 2019 m. liepos 07 d.
ir lieka audito priežiūroje.
Pakartotinis sertifikavimas bus atliekamas prieš 2017 m. gegužės 20 d.
26 leidimas. Sertifikuojamas nuo 1997 m. sausio 28 d.

Sertifikavimas yra grindžiamas ataskaita, kurios numeris: GB/PC05884

Igaliota

/parašas/

SGS Jungtinė Karalystė Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA JK
Tel. +44 (0) 1934 522917 faks. +44 (0) 1934 522137 www.sgs.com

SGSCE 01 0311 M2

KOPIJA TIKRA



CE sertifikatas, visiška kokybės užtikrinimo sistema: GB97/9239, tęsinys

FLECIXARE MEDICAL Ltd

DIREKTYVOS 93/42/EEC

Dėl medicinos priemonių, II priedas (išskyrus 4 skyrių)

26 leidimas

Detali sritis

Nesterilūs: kvėpavimo sistemos; drėkinimo kontūrai; intubacinio vamzdelio prailgintojai; deguonies terapijos ir aerozolinės kaukės; deguonies vamzdeliai; drėkintuvai; HME filtrai; gaivinimo prijungėjai prie medicinos priemonių; anglies dioksido absorbentas; Maxineb kompresorius.

Sterilūs: endotrachėjiniai vamzdeliai; drėkinimo kameros; kvėpavimo sistemos; Sterilios vienkartinio ir daugkartinio naudojimo laringinės kaukės, nazofaringiniai pravedėjai (Nasosafe); sterilios vienkartinio naudojimo Hall Lock spinalinės adatos ir spinalinių adatų rinkiniai; sterilūs silikoniniai Foley kateteriai; sterilūs lateksiniai Foley kateteriai. Sterilūs bužiai ir sterilūs stiletai, sterilūs atsiurbimo kateteriai su vakuumo kontrole. Sterilūs vienkartinio naudojimo atsiurbimo jankaueriai. Sterilus AeroCath drenavimo rinkinys nosies chirurgijai. Sterilūs kvėpavimo filtrai, sterilūs HME filtrai.

Norint parduoti III klasės medicines priemones, pagal II priedą (4 skyrių) galiojantis CE kūrėjo sertifikatas yra privalomas reikalavimas kiekvienai priemonei kaip šio sertifikato priedas.

KOPIJA TIKRA



EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Medical devices as per attachment 1

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

This certificate is valid from 01 April 2016 until 31 March 2021

Report No.: 0521FS28F
Process No.: QS - 0521
Certificate No.: 0521GB410160331

Hamburg, 31 March 2016

MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

KOPIJA TIKRA



2018-07-16

Viešųjų pirkimų specialistė
Greta Rumševičiūtė

Attachment 1
EC-Certificate of Conformity
QS - 0521

This attachment is valid only in connection with certificate No: 0521GB410160331

- **Sets for autologous transfusion**
- **Bacterial-and viral filters**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Disinfectants**
- **3-way stopcocks**
- **Feeding tubes, tubes for small intestine and suction catheters**
- **Loops**
- **Intra uterine pessaries (IUP)**
- **Artificial noses (HME) with O2-connector and their accessories**
- **Nasal splints**
- **Ventilation tubes**
- **Pessaries**
- **Pump tubing systems and their accessories**
- **Redon-systems**
- **Oxygene cannulas**
- **Fecal management systems**
- **Thoracic and trocar catheters**
- **Tracheostomy cannulas and stents**
- **Transfusion devices for blood bags**
- **Urine drainage systems**

Hamburg, 31 March 2016

MEDCERT Certification Body
(Markus Bianchi)

KOPIJA TIKRA

2018-07-16



MED/CERT

CE Sertifikatas

Notifikuojanti įstaiga

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburgas – Vokietija

patvirtina, kad

Primed Halberstadt Medizintechnik GmbH
Straße des 20. juli 1 – 38820 Halberstadt
Vokietija

įdiegė ir pritaiko Kokybės valdymo sistemą,
susijusią su **medicinos priemonių atitikimu metrologiniams reikalavimams**
šiems produktams/produktų kategorijoms:

Žr. Priede

Auditas patvirtino kokybės valdymo sistemos atitikimą

Medicinos priemonių direktyvos 93/42/EEC
II Priedui, iškyrus 4 skirsnį

Sertifikatu tikimasi, kad įmonė pritaiko ir laikosi Kokybės valdymo sistemos pagal minėtąjį priedą.
Sertifikato licenzija yra prižiūrima MEDCERT.

Šis sertifikatas galioja iki 2021 m. kovo 31 d.
Hamburgas, 2016 m. Kovo 31 d.

Proceso Nr. QS - 0521
Sertifikato Nr.: 0521 GB410160331
MEDCERT identifikacijos Nr.: 0482

/Parašas/
MEDCERT sertifikavimo institucija
(Markus Bianchi)



MED/CERT
Priedas
Prie CE atitikties sertifikato
QS-0521

Šis priedas galioja tik kartu su sertifikatu nr.: 0521 GB410160331

- **Rinkiniai autologinei transfuzijai**
- **Anti-bakteriniai/-virusiniai filtrai**
- **Brachiterapiniai kateteriai**
- **Brachiterapinės adatos su auksinėmis žymomis**
- **Dezinfekantai**
- **Trijų krypčių kraneliai**
- **Maitinimo vamzdeliai, vamzdeliai plonosioms žarnoms, atsiurbimo kateteriai**
- **Kilpos**
- **Dirbtinės nosys su O₂ konektoriumi ir jų priedai**
- **Nazaliniai įtvarai**
- **Ventiliaciniai vamzdeliai**
- **Pesarai**
- **Pumpavimo vamzdelių sistemos ir jų priedai**
- **Redon sistemos**
- **Deguonies kaniulės**
- **Išmatų surinkimo sistemos**
- **Krūtininiai ir troakariniai kateteriai**
- **Tracheostominės kaniulės ir stentai**
- **Tranfuziniai prietaisai kraujo maišeliams**
- **Šlapimo drenavimo sistemos**

Hamburg, 2016 m. kovo 31 d.

/parašas/

Medcert Sertifikavimo įmonė
Markus Bianchi





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 14 09 86658 003

Manufacturer: **Suzhou Shuangfei Technical Products Factory**
 No.269, Longxiang Road, Meiyuan Community
 Wujiang District
 215225 Suzhou City, Jiangsu Province
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
 Eiffestraße 80
 20537 Hamburg
 GERMANY

Product Category(ies): **Wooden Tongue Depressors,
 Wooden Ayre Spatulas,
 Cotton Tipped Applicators**

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.: SH14571EXT01

Valid from: 2014-12-22

Valid until: 2019-12-21



Hans-Heiner Junker

Date, 2014-11-17

KOPIJA TIKRA

2010-07-16

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

Page 1 of 2





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 14 09 86658 003

Facility(ies):

**Suzhou Shuangfei Technical Products Factory
No.269, Longxiang Road, Meiyang Community,
Wujiang District, 215225 Suzhou City, Jiangsu
Province, PEOPLE'S REPUBLIC OF CHINA**

ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICAT

A1 / 04.11





Product Service

CE-SERTIFIKATAS**Produkto kokybės užtikrinimo sistema**

Medicinos prietaisų direktyvos 93/42/EEC priedas V

Nr. G2S 14 09 86658 003**Gamintojas:****Suzhou Shuangfei****Technical Products Factory**

Nr. 269, Longxiang Road, Meiyang Community

Wujiang miestas

215225 Suzhou miestas, Jiangsu Province

KINIJOS LIAUDIES RESPUBLIKA

CE Atstovas:**Shanghai International Trading****Corp.GmbH (Europa)**

Eiffestraße 80

20537 Hamburgas

Vokietija

Produkto kategorija (-os)**Medinės liežuvio mentelės****Medinės vaginalinės mentelės****Medvilne dengti aplikatoriai**

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH patvirtina, kad prieš tai paminėtas gamintojas įdiegė kokybės užtikrinimo sistemą: kūrimui, gamybai ir galutiniam patikrinimui prieš tai minėtiems produktams/produktų kategorijoms pagal medicinos prietaisų direktyvos 93/42/EEC V priedo III skyrių. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. Dėl IIB ir III klasės produktų, papildomas priedas III yra privalomas. Taip pat žr. kitame lape.

Protokolo Nr.:

SH14571EXT01

Galioja nuo:

2014-12-22

Galioja iki:

2019-12-21

Data, 2014-11-17

/parašas/

Hans-Heiner Junker



TÜV SÜD Product Service GmbH yra notifikuota įstaiga pagal Tarybos direktyvą 93/42/EEC dėl medicinos priemonių, kurios identifikavimo numeris yra 0123.

Puslapis 1 iš 2



CE-SERTIFIKATAS

Produkto kokybės užtikrinimo sistema

Medicinos prietaisų direktyvos 93/42/EEC priedas V

Nr. G2S 14 09 86658 003



Product Service

Gamykla(os):

Suzhou Shuangfei Technical Products Factory
Nr. 269, Longxiang Road, Meiyang Community,
Wujiang, 215225 Suzhou miestas, Jiangsu sritis
KINIJOS LIAUDIES RESPUBLIKA

Puslapis 2 iš 2

KOPIJA TIKRA



2018-07-16

Greif

Užsakymų pirkimų specialistė
Iveta Rumševičiūtė



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 15 07 56846 023

Manufacturer: **Shenzhen Ant Hi-Tech Industrial Co., Ltd.**

18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

High Pressure Syringe, Manifold, Pressure Connecting Tube, Introducer Set, Disposable Pressure Transducer, Positive Needlefree Connector, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V.catheter for single use, Sterile Intravenous needles for single use, Filling Device.

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.: BJ1581107

Valid from: 2015-11-16

Valid until: 2020-11-15



KOPIJA TIKRA

2018-07-16

Vištyrių pirkimų specialistė
Greta Rumševičiūtė

Date, 2015-09-07

Hans-Heiner Junker

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

Page 1 of 2





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 15 07 56846 023

Facility(ies):

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
46 Keji Ave., Yuquan Industrial Park, Fenggang, 523696
Dongguan, PEOPLE'S REPUBLIC OF CHINA





Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 15 08 38814 060

Manufacturer: Well Lead Medical Co., Ltd.

C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): For detailed information see attachment

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

Report No.: SH1508017

Valid from: 2015-08-24
Valid until: 2020-08-23



Hans-Heiner Junker

Date, 2015-11-26

KOPIJA TIKRA

2018-07-16

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

Page 1 of 3





Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 15 08 38814 060

Facility(ies):

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

Well Lead Medical Co., Ltd.
No 47 Guomao Avenue South, 511434 Panyu,
Guangzhou, PEOPLE'S REPUBLIC OF CHINA



Attachment for Certificate No G2 15 08 38814 060

Supplement 001 dated 2015-11-26



Product Service

For the product(s)/product category (ies):

Urethral Catheters and Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Intubating Stylets, Laryngeal Mask Devices, Tracheobronchial Tubes, Reinforced Endotracheal Tubes, Nebulizers, Oxygen Masks, Non-Rebreath Masks, Tracheostomy Masks, Aerosol Masks, Multi-vent Masks, Endotracheal Tube Introducers, Nasal Oxygen Cannulas, Stylets, Disposable Air Cushion Face Masks, Endotracheal Tube Kits, HMEF(Heat and Moisture Exchanger Filters), Manual Resuscitators, Drainage Systems, Oxygen Catheters, Silicone Tubes, Endobronchial Blocker Tubes, Extraction Bags(Operation Use), Ureteral Stent Sets, Silicone Drainage Systems, Endotracheal Tubes with Evacuation Lumen, Suction Catheters, Feeding Tubes, Stomach Tubes, Silicone Stomach Tubes, Disposable Self-Catheterization Systems, Capnography CO₂ Sampling Masks, O₂+CO₂ Sampling Cannulas, Non-invasive Positive Pressure Ventilation Masks, Suction Tubes of Oral Care, Bile T-Tubes, Fecal Management Systems, Self Hydrophilic Catheters, Ureteral Access Sheaths, Ureteral Dilation Balloon Catheters, Extracorporeal Circulation Conduct of Blood Purification Apparatus, Urodynamic Catheters, Rectal Pressure Catheters, Anesthetic Breathing Circuits, Dilation Sets, Suction-Evacuation Access Sheaths, Bladder Puncture Fistula, Guide Wire

Munich, CRT2, 2015-11-26

Hans-Heiner Junker

Page 3 of 3

KOPIJA TIKRA



CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB (MDD), Priedas V
(IIa, IIb ar III klasės prietaisai)

Nr. G1 15 08 38814 060

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

EB atstovas **Shanghai International Holding Corp. GmbH (Europa)**
Eiffestraße 80
20537 Hamburgas
VOKIETIJA

Produkto kategorija(os): **Detalesnė informacija priede**

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 V Priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. Iib ir III klasės produktams galioja papildomas III priedas. Taip pat žr. kitame lape.

Protokolo Nr. SH1508017

Galioja nuo: 2015-08-24

Galioja iki: 2020-08-23

Data, 2015-11-26 /parašas/
Hans-Heiner Junker

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



CE SERTIFIKATAS

Pilna kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB (MDD), Priedas V
(IIa, IIb ar III klasės prietaisai)

Nr. G2 15 08 38814 060

Gamykla (-os):

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

Well Lead Medical Co., Ltd.
Nr. 47 Guomao Avenue South, 511434 Panyu,
Guangzhou, KINIJOS LIAUDIES RESPUBLIKA

KOPIJA TIKRA



Priedas prie sertifikato Nr. G2 15 08 38814 060

Papildytas 001 data 2015 – 11- 26

Galioja šiems produktams:

Ureteriniams kateriams ir trachėjos vamzdeliams, nelatono kateteriams, sujungimo vamzdeliams su jankauerio rankena, intubaciniams stiletams, laringinėms kaukėms, tracheobronchiniam vamzdeliams, armuotiems endotrachėjiniams vamzdeliams, purkštuvams, deguonies kaukėms, neinvazinėms kaukėms, tracheostominėms kaukėms, aerolinėms kaukėms, daugiaventiliacinėms kaukėms, endotrachėjinių vamzdelių stiletams, nosinėms deguonies kaukėms, stiletams, vienkartinėms veidinėms anestezinėms kaukėms, endotrachėjinių vamzdelių rinkiniams, šilumos ir drėgmės filtrams, ambu maišams, drenavimo sistemoms, deguonies kateteriams, silikoniniams vamzdeliams, endobronchiniam vamzdeliams, maišeliai ekstrakcijai, ureterinių stentų rinkiniams, silikoninėms drenavimo sistemoms, endotrachėjiniams vamzdeliams su kanalu, atsiurbimo kateteriams, maitinimo vamzdeliams, skrandžio zondams, silikoniniams skrandžio zondams, vienkartinėms kateterizavimo sistemoms, kanografinėms CO2 matavimo kaukėms, O2 + CO2 matavimo kaniulėms, Ne invazinėms teigiamo slėgio kaukėms, atsiurbimo vamzdeliams burnos priežiūrai, tulžies T-vamzdeliams, fekalinėms sistemoms, hidrofiliniams kateteriams, ureteriniams apvalkalams, ureteriniams dilataciniams balioniniams kateteriams, ekstrakorporinės cirkuliacijos kraujo valymo aparatui, urodinaminiams kateteriams, rektaliniams slėgio kateteriams, anesteziniam kvėpavimo kontūram, dilatacijos rinkiniams, evakuacijos siurbimo priemonėms, pūslės punkcijos fistulėms, vieliniams pravedėjams,

Miunchenas, CRT2, 2015-11-26

/parašas/

Hans-Heiner Junker

Puslapis 3 iš 3





EC Design-Examination Certificate



according to directive 93/42/EEC,
annex II (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC annex II.4 as documented in the report mentioned in the Annex.

Product: **Brain Pro: biopsy, central nervous system, brain biopsy, cannulas**

Date of the first certification: 2010-03-22

Date of the last recertification: 2015-03-22

This certificate is valid until: 2020-03-21

Certificate registration No.: 51268-23-B1



DEKRA Certification GmbH
Stuttgart, 2015-03-20
Notified Body ID-number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-296.10.01

Loss of fulfillment of conditions set out in the Certification Agreement may render this certificate invalid

KOPIJA TIKRA





Annex to the EC design examination certificate 51268-23-B1 dated 2015-03-20

Revision status: 0 Date: 2015-03-22 Page 1 of 1



Report number: 51268-P2-01

Product: BrainPro: biopsy, central nervous system, brain biopsy, cannulas

Intended use:

The cannulas are intended for use in stereotactic and other guided biopsy of brain tissue.

Technical data:

The Cannulas are made from stainless steel or titanium and available in the following variants:

BrainPro Biopsy Cannula Set for stereotaxic brain biopsy		
For CT-controlled application, lateral opening 10mm, rotatable, 10 ml syringe, stopcock, ruler 25 cm.		
Ref.	Brand / device	Specification
1153-2L250	BrainPro Biopsy Cannula Set for stereotaxic brain biopsy	Ø 1,8 x 250 mm
1153-2L200	BrainPro Biopsy Cannula Set for stereotaxic brain biopsy	Ø 1,8 x 200 mm
BrainPro Biopsy Cannula Set for stereotaxic brain biopsy accordance to Merlo		
Guiding cannula Ø 2,3 x 230, graduated with stylet, bipartite biopsy cannula Ø 1,8 x 260 mm with lateral opening 10mm, rotatable, 10 ml syringe, stopcock, ruler 25 cm, ejection stylet.		
Ref.	Brand / device	Specification
1153-4L230	BrainPro Biopsy Cannula Set for stereotaxic brain biopsy	Ø 2,3 x 230 mm
BrainPro Titanium Biopsy Set for open MRI application		
Bipartite biopsy cannula, with lateral opening 10mm, rotatable, 10 ml syringe, stopcock, ruler 25 cm, ejection stylet.		
Ref.	Brand / device	Specification
1153-3L110	BrainPro Titanium Biopsy Set	Ø 1,8 x 150 mm
1153-3L150	BrainPro Titanium Biopsy Set	Ø 1,8 x 110 mm
Anchoring – and guidance instrument for BrainPro brain biopsy cannulae with selfcutting titanium thread.		
1153-90011	BrainPro-Access Ø 11 mm for drill holes Ø 10 – Ø 12,5 mm	
1153-90014	BrainPro-Access Ø 14 mm for drill holes Ø 14 – Ø 16 mm	
BrainPro Biopsy Kit, customized		
Outer cannula Ø 2,5 x 210 mm, with lateral window (8 mm), inner cannula with cutting specimen chamber, depth marker adjustable, ejection stylet, injection tube Ø 2,7 x 400 mm, Luer lock, 10 ml syringe, stopcock valve, ruler.		
Item number	Brand / device	Specification
1153-2S210	BrainPro Biopsy Cannula Kit	Outer cannula: Ø 2,5 x 210 mm
Outer cannula Ø 1,8 (16G) x 235 mm, with lateral window (10 mm), navigation marker proximally fixed, inner cannula with cutting specimen chamber, 10 ml syringe, stopcock valve, ruler.		
Item number	Brand / device	Specification
41778B	BrainPro Biopsy Cannula Kit	Outer cannula: Ø 1,8 x 235 mm
41779B	BrainPro Biopsy Cannula Kit	5 pieces of item number 41778B

The sterile disposable biopsy kit contains the following products:

- 2-component Biopsy cannula (3-component acc. to Merlo – with guiding cannula)
- 2-way-cock
- optional: cannula rider/ fixation/ depth stop
- Ruler (stainless steel, PC)
- LOR Syringe with stopcock
- Optional: stylet / ejector and injection tube / injection hose
- Optionally equipped with markers/ navigation aid

This document may only be reproduced and distributed complete!

KOPIJA TIKRA

2018-07-16





EC Certificate

Full Quality Assurance System

Certificate No.:
11168-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
04 March 2020

This is to certify that the quality system of:

Harsoria Healthcare Pvt. Ltd.

110 – 111, Phase – IV, Udyog Vihar,
Gurgaon – 122 015, Haryana, India

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

Sterile Disposable Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

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

Place and Date:
Høvik, 12 October 2017



NORWEGIAN
ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

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

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

MSD-CO-078

DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA

Page 1 of 4





EC Certificate

Full Quality Assurance System

Certificate No.:
11168-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
04 March 2020

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 5262-2014-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-12

Products covered by this Certificate:

Product Description	Product Name	Class
IV Cannula with Catheter with or without injection valve and with or without wings	Sizes 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Safety IV Cannula with Catheter with or without injection valve and with or without wings	Sizes 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
AV Fistula Needle Set	Variant- Twin Set, Single in Size- 14G, 15G, 16G, 17G, 18G	IIa
Injection Stopper		IIa
3 Way Stop Cock with/without Extension Tubes	Lipid/Non-Lipid Resistant with Tube Length 10cm, 50cm, 100cm, 150cm, 200cm, 250cm	IIa
Extension Tube	10cm, 25cm, 50cm, 75cm, 100cm, 150cm, 200cm, 250cm	IIa
Flow Regulator		IIa
Luer Cap		IIa
Combi Luer Lock		IIa
Obturator	12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Intravenous Infusion Set (I.V. Set)	With or without Air Vent, Luer Lock and Flow Regulator	IIa



KOPIJA TIKRA

2018-07-16

[Signature]
Sveiki pirkimų specialistė
Iveta Rumševičiūtė



EC Certificate

Full Quality Assurance System

Certificate No.:
11168-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
04 March 2020

Blood Transfusion Set (B.T. Set)	Variant - Single chamber with/without Air Vent	Ila
----------------------------------	--	-----

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Harsoria Healthcare Pvt. Ltd.	110 – 111, Phase – IV, Udyog Vihar, Gurgaon – 122 015, Haryana, India.

EU Representative

mdi Europa GmbH, Langenhagener Strasse 71, D 30855, Hannover-Langenhagen, Germany
email: info@mdi-europa.com



KOPIJA TIKRA

2018-07-16

Greta Rumševičiūtė
Višnių pirkimo specialistė
Greta Rumševičiūtė



EC Certificate

Full Quality Assurance System

Certificate No.:
11168-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
04 March 2020

Terms and conditions

The certificate is subject to the following terms and conditions:

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

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

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

End of Certificate

KOPIJA TIKRA





CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:
1168-2017-CE-IND-NA-PS Rev. 0.0

Projekto Nr:
PRJC-503753-2014-MSL-IND

Galioja iki:
2020 Kovo 04

Šiuo setifikatu patvirtinama, kad kokybės valdymo sistema:

Harsoria Healthcare Pvt. Ltd.
110-111, Phase – IV Udyog Vihar,
Gurgaon – 122 015, Haryana, Indija

kūrimui, gamybai ir galutinei apžiūrai

Sterilių Vienkartinių Medicinos Prietaisų

įvertinta remiantis
atitikties įvertinimo procedūra aprašyta Straipsnyje 11.3.a ir Medicinos prietaisų 93/42/EEC
direktyvos Priede II (išskyrus skyrių 4), atitinka

Skaitykite kitame puslapyje

Vieta ir laikas:
Hovik, 2017-10-17



DNV GL NEMKO PRESAFE AS
/parašas/
Alessandra Rinna

KOPIJA TIKRA





CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:
1168-2017-CE-IND-NA-PS Rev. 0.0

Projekto Nr:
PRJC-503753-2014-MSL-IND

Galioja iki:
2020 Kovo 04

Teisingumas

1993-06-14 93/42/EEC direktyvos taikymas, Norvegijos sveikatos ir priežiūros tarnybos ministerijos pasirinkta kaip „Forskrift Medisinsk Utstyr“.

Sertifikato išsklotinė

Peržiūra	Aprašymas	Išleidimo data
0.0	Pakeičia DNVGL (NB 0434) Sertifikatą Nr.: 5262-2014-CE-IND-NA 0.0 po notifikuotos įstaigos funkcijų pakeitimo į DNV GL Nemko Presafe AS (NB 2460)	2017-10-12

Šiuo sertifikatu apsaugoti gaminiai

Gaminio aprašymas	Gaminio pavadinimas	Klasė
Intraveninė kaniulė su kateteriu, su arba be injekcijos lizdo, su arba be sparnelių	Dydžiai 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	Ila
Saugi Intraveninė kaniulė su kateteriu, su arba be injekcijos lizdo, su arba be sparnelių	Dydžiai: 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	Ila
AV fistulinės adatos rinkinys	Galimas dvigubas rinkinys, Vieno dydžio – 14G, 15G, 16G, 17G, 18G	Ila
Injekcinis kamštukas		Ila
3-jų krypčių kranelis su/be prailginimo linijų	Atsparus/Neatsparus lipidams, Prailginimo linijos 10cm, 50cm, 100cm, 150cm, 200cm, 250cm	Ila
Prailginimo linija	10cm, 25cm, 50cm, 75cm, 100cm, 150cm, 200cm, 250cm	Ila
Dozatorius		Ila
Kamštelis		Ila
Combi Luer Lock kamštelis		Ila
Obturatorius	12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	Ila
Intraveninės infuzijos sistema	Su/be oro vožtuvo, Luer Lock jungties ir dozatoriaus	Ila
Kraujo transfuzijos sistema	Vienos kameros, su/be oro	Ila





CE SERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:
1168-2017-CE-IND-NA-PS Rev. 0.0

Projekto Nr:
PRJC-503753-2014-MSL-IND

Galioja iki:
2020 Kovo 04

	vožtuvo	
--	---------	--

Pilnas prietaisų sąrašas pateikiamas Notifikuotos įstaigos.

Sertifikato patvirtintos vietos

Vieta	Adresas
Harsoria Healthcare Pvt. Ltd.	4F110-111, Phase – IV Udyog Vihar, Gurgaon – 122 015, Haryana, Indija

Europos sąjungos įgaliotinis

Įmonės pavadinimas	Adresas
Mdi Europa GmhH	Langenhagener Str. 71, 30855 Langenhagen, Vokietija

KOPIJA TIKRA





CE CERTIFIKATAS – PILNOS KOKYBĖS UŽTIKRINIMO SISTEMA

Sertifikato Nr:
1168-2017-CE-IND-NA-PS Rev. 0.0

Projekto Nr:
PRJC-503753-2014-MSL-IND

Galioja iki:
2020 Kovo 04

Sąlygos ir terminai:

Sertifikatui galioja šios sąlygos ir terminai:

- Remiantis 85/374/EEC direktyva, bet kuris gamintojas (tiksliau ieškokite 2001/95/EC) yra atsakingas už prastos gaminio kokybės sukeltą žalą.
- Sertifikatas galioja tik anksčiau išvardintiems gaminiams.
- Gamintojas privalo įvykdyti pareigas, susijusias su kokybės sistema bei laikytis jų, užtikrindamas jų efektyvumą ir tinkamumą.
- Gamintojas privalo informuoti vietinę Presafe įstaigą apie bet kokius kokybės sistemos atnaujinimus; Presafe įvertina pasikeitimus ir nusprendžia ar sertifikatas vis dar gali būti laikomas galiojančiu.
- Siekiant įvertinti ar gamintojas taiko kokybės sistemą, atliekamos periodinės apžiūros.

Šioms sąlygoms esant sertifikatas laikomas negaliojančiu:

- Esant kokybės sistemos pakitimams, kurie įtakoja gamybą.
- Periodinės apžiūros nėra atliekamos nustatytu terminu.

Atitikties deklaracija ir gaminio ženklėjimas

Siekdamas užtikrinti, kad į sąlygas ir terminus yra atsižvelgiama, gamintojas gali sudaryti atitikties

d
e
k
l
a
r
a
c
i
j
ą

i
r

l
e
g
a
l
i

KOPIJA TIKRA

