CERTIFICATE

AT Sertifikası
Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-19-588

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

MEDİTERA TIBBİ MALZEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TÜRKİYE

Ürünler: Solunum Devreleri, Isıtıcı Telli Devre, Anestezi Balonu, Solunum Maskesi, Filtre, IV Set ve Konnektörler, Kateter Mount, Enjektör Kilit Adaptörü, Biyosidal Aparatı

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No:	M.5419.02
İlk Yayım Tarihi:	17 Nisan 2019
Son Yayım Tarihi:	14 Nisan 2021
Revizyon Numarası:	02
Son Geçerlilik Tarihi:	16 Nisan 2024

Bu sertifika kapsamında olan Sınıf Is ürünler için Kiwa Belgelendirme Hizmetleri A.Ş., Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

14 Nisan 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

AT Sertifikası Eki:

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika No: 1984-MDD-19-588, Revizyon Numarası: 02

İlgili tıbbi cihazlar;

Ürün: Solunum Devreleri
Tipleri: Ventilasyon Devreleri, Anestezi Devreleri, Özel Devreler, Yarı Kapalı Devreler / APL Valfli Devreler, BPAP Devreler, IPPB Devreler, CPAP Devreler, Proksimal Basınç Hatlı Devreler, Coaxial Devreler, T Devreler, Chambers, Aspiarasyon Hortumları, BVM Resusitatörler, Gaz Örnekleme Hatları, Devreler İçin Nebulizasyon Parçaları

Ürün: Isıtıcı Telli Devreler

Ürün: Anestezi Balonları

Ürün: Solunum Maskesi
Tipleri: Anestezi Maskeleri, Oksijen / Aerosol Terapi Maskeleri

Ürün: Filtre
Tipleri: Solunum Filtreleri

Ürün: IV Set ve Konnektörler
Tipleri: İnfüzyon Setleri, Uzatma Setleri, İnfüzyon Konnektörleri

Ürün: Kateter Mount

Ürün: Enjektör Kilit Adaptörü

Ürün: Biyosidal Aparatı

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

14 Nisan 2021, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-588

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

MEDİTERA TIBBİ MALZEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TURKEY

Products: Breathing Circuits, Heated Wire Circuits, Anestheasia Bags, Breathing Masks, Filters, IV Sets ve Connectors, Catheter Mounts, Syringe Lock Adaptor, Biocidal Applicator

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5419.02
Date of first issue: 17 April 2019
Date of last issue: 14 April 2021
Revision Number: 02
Expiry Date: 16 April 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V for Class Is devices covered by this certificate.

14 April 2021, Istanbul, Turkey

Müntesem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-588, Revision Number: 02

Concerned medical devices;

Product: Breathing Circuits
Types: Ventilation Circuits, Anestheasia Circuits, Special Circuits, Semi-Closed Circuits / APL Valve Circuits, BPAP Circuits, IPPB Circuits, CPAP Circuits, Proximal Pressure Line Circuits, Coaxial Circuits, T Circuits, Chambers, Aspiration Tubes, BVM Resuscitators, Gas Sampling Lines, Nebulizer Parts for Breathing Circuits

Product: Heated Wire Circuits

Product: Anestheasia Bags

Product: Breathing Masks
Types: Anestheasia Masks, Oxygen / Aerosol Therapy Masks

Product: Filters
Types: Breathing Filters

Product: IV Sets ve Connectors
Types: Infusion Sets, Extension Lines, Infusion Connectors

Product: Catheter Mounts

Product: Syringe Lock Adaptor

Product: Biocidal Applicator

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

14 April 2021, Istanbul, Turkey

Head of Notified Body
Muhteşem Gökhan Yücel

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CE sertifikatas

Produkcijos Kokybės Užtikrinimo sistema
pagal Medicinos priemonių direktyvą 93/42/EEC priedas-V

Sertifikato numeris 1984-MDD-19-588

Patvirtiname, kad kokybės įvertinimas buvo atliktas laikantis nacionalinių teisės aktų, kurie taikomi toliau pasirašiusiam subjektui, reikalavimų, pagal Direktyvos 93/42 dėl medicinos prietaisų V priedą. Mes patvirtiname, kad produkcijos kokybės sistema atitinka atitinkamas minėtų teisės aktų nuostatas.

Rengėjas:

ALTERA TIBBI MALZEME
SANAYI VE TICARET ANONIM SIRKETI

IBNI MELEK OSB. MH. TOSBI YOL 4SK. NO:29 35900 TIRE /IZMIRAS- TURKIJA

Produktai: Kvėpavimo kontūrai, šildomi kontūrai, anesteziniai krepšiai, kvėpavimo kaukės, filtrai, IV rinkiniai ir konektoriai, paciento jungtys, švirkštų adapteriai, biocidinis aplikatorius

Produktai išvardinti viršuje, yra šio sertifikato dalis, kurį sudaro vienas puslapis. Sertifikatas galioja iki galiojimo pabaigos, sėkmingai atlikus periodinius priežiūros auditus. Prašome susisiekti su Kiwa, dėl detalių.

Ataskaitos nr: M.5419.02
Pirmo išdavimo data: 2019 m balandžio 17 d.
Paskutinio išdavimo data: 2021 m balandžio 14 d.
Peržiūros numeris: 02
Galioja iki: 2024 balandžio 16 d.

„Kiwa sertifikavimo paslaugos“ patikrino kokybės sistemą, apibrėžtą gamybos aspektais, susijusiais su sterilių sąlygų užtikrinimu ir palaikymu pagal MDD V priedą, ir nustatė, kad kokybės sistema atitinka MDD V priedo reikalavimus, taikomus priemonėms, kurioms taikomas šis sertifikatas.

<parašas>
Notifikuotosios įstaigos vadovas
Muhtesem Gokhan Yucel

2021 m balandžio 14 d., Stambulas, Turkija

<Kiwa rekvizitai>

CE sertifikato priedas:
Produkcijos Kokybės Sistema pagal Medicinos Priemonių direktyvą 93/42/ECC Priedas V
Sertifikato numeris: 1984-MDD-19-588, Peržiūros numeris: 02

Susijusios medicinos priemonės:

Produktas: Kvėpavimo kontūrai
Tipai: Ventiliavimo kontūrai, anestezijos kontūrai, specialūs kontūrai, pusiau uždari kontūrai/ APL vožtuvo kontūrai, BPAP kontūrai, IPPB kontūrai, CPAP kontūrai, proksimalinių spaudimo linijų kontūrai, koaksialiniai kontūrai, T kontūrai, kameros, aspiracijos vamzdeliai, gaivinimo maišai, dujų monitoravimo linijos, nebulaizerių dalys kvėpavimo kontūrams.

Produktas: Šildomi kontūrai

Produktas: Anesteziniai krepšiai

Produktas: Kvėpavimo kaukės
Tipai: Anestezinės kaukės, deguonies/ aerozolio terapijos kaukės

Produktas: Filtrai
Tipai: Kvėpavimo filtrai

Produktas: IV rinkiniai ir konektoriai
Tipai: Infuzijos rinkiniai, prailginimo linijos, infuzijos konektoriai

Produktas: Paciento jungtys

Produktas: Švirkšto adapteris

Produktas: Biocidinis aplikatorius

„Kiwa Sertifikavimo paslaugos“ yra notifikuotoji įstaiga pagal Tarybos direktyvą medicinos priemonėms 93/42/EEC su identifikavimo numeriu: 1984

<parašas>
Notifikuotosios įstaigos vadovas
Muhtesem Gokhan Yucel

2021 m. balandžio 14 d., Stambulas, Turkija

<Kiwa rekvizitai>

CERTIFICATE

AT Sertifikası
Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-19-588

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

MEDİTERA TIBBİ MALZEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TÜRKİYE

Ürünler: Solunum Devreleri, Isıtıcı Telli Devre, Anestezi Balonu, Solunum Maskesi, Filtre, IV Set ve Konnektörler, Kateter Mount, Enjektör Kilit Adaptörü

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No:	M.5419.01
İlk Yayım Tarihi:	17 Nisan 2019
Son Yayım Tarihi:	02 Ekim 2019
Revizyon Numarası:	01
Son Geçerlilik Tarihi:	16 Nisan 2024

Bu sertifika kapsamında olan Sınıf Is ürünler için Kiwa Belgelendirme Hizmetleri A.Ş., Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

02 Ekim 2019, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

AT Sertifikası Eki: **Sayfa 1/1**

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika No: 1984-MDD-19-588, Revizyon Numarası:01

İlgili tıbbi cihazlar;

Ürün: Solunum Devreleri **Sınıf:** IIa
Tipleri: Ventilasyon Devreleri, Anestezi Devreleri, Özel Devreler, Yarı Kapalı Devreler / APL Valfli Devreler, BPAP Devreler, IPPB Devreler, CPAP Devreler, Proksimal Basınç Hatlı Devreler, Coaxial Devreler, T Devreler, Chambers, Aspiarasyon Hortumları, BVM Resusitatörler, Gaz Örnekleme Hatları, Devreler İçin Nebulizasyon Parçaları

Ürün: Isıtıcı Telli Devreler **Sınıf:** IIa

Ürün: Anestezi Balonları **Sınıf:** IIa

Ürün: Solunum Maskesi **Sınıf:** IIa
Tipleri: Anestezi Maskeleri, Oksijen / Aerosol Terapi Maskeleri

Ürün: Filtre **Sınıf:** IIa
Tipleri: Solunum Filtreleri

Ürün: IV Set ve Konnektörler **Sınıf:** IIa
Tipleri: İnfüzyon Setleri, Uzatma Setleri, Infüzyon Konnektörleri

Ürün: Kateter Mount **Sınıf:** IIa

Ürün: Enjektör Kilit Adaptörü **Sınıf:** Is

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

02 Ekim 2019, İstanbul, Türkiye

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com.tr

CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-588

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

MEDİTERA TIBBİ MALZEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TURKEY

Products: Breathing Circuits, Heated Wire Circuits, Anestheasia Bags, Breathing Masks, Filters, IV Sets ve Connectors, Catheter Mounts, Syringe Lock Adaptor

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5419.01
Date of first issue: 17 April 2019
Date of last issue: 02 October 2019
Revision Number: 01
Expiry Date: 16 April 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V for Class Is devices covered by this certificate.

02 October 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-588, Revision Number:01

Concerned medical devices;

Product: Breathing Circuits **Class:** IIa
Types: Ventilation Circuits, Anestheasia Circuits, Special Circuits, Semi-Closed Circuits / APL Valve Circuits, BPAP Circuits, IPPB Circuits, CPAP Circuits, Proximal Pressure Line Circuits, Coaxial Circuits, T Circuits, Chambers, Aspiration Tubes, BVM Resuscitators, Gas Sampling Lines, Nebulizer Parts for Breathing Circuits

Product: Heated Wire Circuits **Class:** IIa

Product: Anestheasia Bags **Class:** IIa

Product: Breathing Masks **Class:** IIa
Types: Anestheasia Masks, Oxygen / Aerosol Therapy Masks

Product: Filters **Class:** IIa
Types: Breathing Filters

Product: IV Sets ve Connectors **Class:** IIa
Types: Infusion Sets, Extension Lines, Infusion Connectors

Product: Catheter Mounts **Class:** IIa

Product: Syringe Lock Adaptor **Class:** Is

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

02 October 2019, Istanbul, Turkey

Head of Notified Body
Muhteşem Gökhan Yücel

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

Kiwa Belgelendirme Hizmetleri A.Ş.
İ.T.O.S.B 9. Cadde No: 15
Tepeören Mevkii PK 34959
Tuzla İstanbul
Türkiye

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www.kiwa.com
www.1kiwa.com

Notified Body Confirmation Letter

Subject/*Konu*: Continuation of Surveillance Audits in the Context of MDD Certificate Extension
MDD Sertifikasının Uzatılması Bağlamında Gözetim Denetimlerinin Devamı

Date/*Tarih*: 26.02.2024

Reference No/*Referans Numarası*: MY-24-002703

To whom it may concern,
Sayın Yetkili,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.
AB) 2017/745 sayılı ve (AB) 2017/746 sayılı Tüzükleri belirli Tıbbi cihazların ve in vitro tanı amaçlı Tıbbi cihazların geçiş hükümlerini tadil eden 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü" Sayılı Yönetmelik çerçevesinde, resmi bir başvurunun durumunun onaylanması, yazılı anlaşma ve uygun gözetim.

This letter confirms that, **Kiwa Cermet Italia SPA** a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0476** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement **MDR Agreement No: CERBO0147622** in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer
*Bu mektup, (AB) 2017/745 Sayılı Yönetmelik (MDR) kapsamında atanan ve NANDO'da **0476** numarası ile tanımlanan bir Bildirilmiş Kuruluş (NB) olan **Kiwa Cermet Italia SPA**'nın, MDR'nin Ek VII'nin 4.3. maddesi birinci alt paragrafına uygun olarak alınan resmi bir başvuruyu ve MDR'nin Ek VII'nin 4.3. maddesi ikinci alt paragrafına uygun olarak imzalanan **MDR Sözleşme No: CERBO0147622** yazılı anlaşmayı aşağıdaki üretici ile gerçekleştirdiğini teyit etmektedir.*

Meditera Tıbbi Malzeme San. ve Tic. A.Ş.
İbni Melek OSB Mah. TOSBİ Yol 4 Sok. No: 29 Tire Organize Sanayi Bölgesi, Tire / İzmir / Turkey

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive
93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been with-drawn, this letter also confirms that:
- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

90/385/EEC Sayılı Direktif (AIMDD) veya 93/42/EEC Sayılı Direktif (MDD) kapsamında düzenlenen ve 26 Mayıs 2021 tarihinden sonra ve 20 Mart 2023 tarihinden önce süresi dolan ve geri çekilmemiş sertifikalı cihazlar durumunda, bu mektup ayrıca şunları da teyit etmektedir:

-Üretici, MDD/AIMDD sertifikasının süresi dolmadan önce MDR kapsamında yazılı anlaşmayı imzalamıştır; veya
-Bir AB üye devletinin yetkili makamının, MDR'nin 59(1) maddesine uygun olarak bir muafiyet verdiğine dair kanıt sunulmuştur; veya
-Bir AB üye devletinin yetkili makamının, MDR'nin 97(1) maddesine uygun olarak geçerli uygunluk değerlendirme prosedüründen muafiyet verdiğine dair kanıt sunulmuştur.

On **10.01.2024**, an application was submitted to our organization for MDD surveillance audits of the products specified in **Annex-I**, and the contract with Reference Number **QUO-188829-X1V2Y5** was signed on **05.02.2024**. In this context, the company's audits will be continued by Kiwa Certification Services Inc. until **26.09.2024**.

***10.01.2024** tarihinde, **Ek-I'de** belirtilen ürünlerin MDD denetim denetimleri için kuruluşumuza başvuruda bulunulmuş ve **05.02.2024** tarihinde **QUO-188829-X1V2Y5** referans numaralı sözleşme imzalanmıştır. Bu bağlamda, şirketin denetimleri Kiwa Belgelendirme Hizmetleri A.Ş. tarafından **26.09.2024** tarihine kadar devam ettirilecektir.*

Annex-I: Certificate Information
Ek-I: Sertifika bilgileri

Notified Body/*Onaylı Kuruluş*	Products */Cihazlar*	Certificate Number/*Sertifika Numarası*	Valid Date/ *Geçerlilik Tarihi*	Regulation */Yönetmelik*
Kiwa Belgelendirme Hizmetleri A.Ş.	-Breathing Circuit/*Solunum Devreleri* - Heated Wire Circuits/*Isıtıcı Telli Devreler* - IV Sets and Connectors/*IV Set ve Konnektörler* - Syringe Lock Adapter/*Şırınga Kilit Adaptörü* - Biocidal Applicator/*Biyosidal Aparatı* - Filters/*Filtre* - Catheter Mounts/*Katater Mount* - Aneshteasia Bags/*Anestezi Balonları* - Breathing Mask/*Solunum Maskesi*	1984-MDD-19-588	16.04.2024	93/42/AT

Kind Regards,
Saygılarımla,
Debuty General Manager
Genel Müdür Yardımcısı
Mehmet Fevzi Gülünay

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

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.* 3524 7139
3526 6208
90

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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 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.* 3524 7139
3526 6208

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
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Essen, 2020-04-20

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

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

Bericht Nr. / *Report No.* 3524 7139
26 6208
26 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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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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.* 3524 7139
3526 6208
5290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
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Essen, 2020-04-20

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

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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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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Essen, 2020-04-20

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 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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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Essen, 2020-04-20

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

TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Turkey

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference	Contact	Direct Dial	Date
No.: 8003060047	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	29 June 2023

Notified Body Confirmation Letter
Reference: 8003060047

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Turkey
SRN Number: TR-MF-000022603

TÜVNORD

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜVNORD i. V. Digital unterschrieben von Mühlenberg Kevin Datum: 2023.07.05 09:16:27 +02'00'

i. V. Kevin Mühlenberg
Head of Projectmanagement
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. A. Digital unterschrieben von Mestmacher Bodo Datum: 2023.07.05 09:08:26 +02'00'

i. A. Bodo Mestmacher
Specialist Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Pressure Monitoring Set	Class IIb	N/A	04232980886
Leukocyte Filter Set	Class IIb	N/A	04232980886
Gamma Leukocyte Filter Set	Class IIb	N/A	04232980886
Thoracenthesis Set	Class IIa	N/A	04232980886
Thoracic Catheter	Class IIa	N/A	04232980886
Arterial Needle	Class IIa	N/A	04232980886
Endotracheal Tube	Class IIa	N/A	04232980886
Reinforced Endotracheal Tube	Class IIa	N/A	04232980886
RAE Endotracheal Tube	Class IIa	N/A	04232980886
Nasogastric Catheter	Class IIa	N/A	04232980886
Stomach Catheter	Class IIa	N/A	04232980886
Feeding Catheter	Class IIa	N/A	04232980886
Manifold / Manifold Pressure	Class IIa	N/A	04232980886
Three -Way Stopcock	Class IIa	N/A	04232980886
Tourniquet Set	Class IIa	N/A	04232980886
IV Cannula	Class IIa	N/A	04232980886
Suction Catheter	Class IIa	N/A	04232980886
Microaggregate Filter Set (Blood Filter Set)	Class IIa	N/A	04232980886
Soft Drain	Class IIa	N/A	04232980886
Oxygen Catheter	Class IIa	N/A	04232980886
Nasal Oxygen Cannula	Class IIa	N/A	04232980886
Oxygen Connecting Tube	Class IIa	N/A	04232980886
Tracheostomy Tube	Class IIa	N/A	04232980886
Extracorporeal PVC Tubing	Class IIa	N/A	04232980886
Extracorporeal Tubing Set	Class IIa	N/A	04232980886
Quick Prime Set	Class IIa	N/A	04232980886
Cardioplegia Set	Class IIa	N/A	04232980886
Wound Drainage Set	Class IIa	N/A	04232980886
Infusion Pump Set	Class IIa	N/A	04232980886
Yankauer Suction Set	Class IIa	N/A	04232980886
Suction Connecting Tube	Class IIa	N/A	04232980886
Surgical Braided Tape	Class IIa	N/A	04232980886
Nelaton Catheter	Class IIa	N/A	04232980886
Tiemann Catheter	Class IIa	N/A	04232980886
Hydrophilic coated uretheral Catheter	Class IIa	N/A	04232980886
IV Filter Set	Class IIa	N/A	04232980886
Aspirators	Class IIa	N/A	04232980886
Blood Transfusion Set	Class IIa	N/A	04232980886
Rectal Catheter	Class IIa	N/A	04232980886
Umbilical Catheter	Class IIa	N/A	04232980886
Angiographic Kit	Class IIa	N/A	04232980886

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
B -Soft Kit	Class IIa	N/A	04232980886
Aortic Punch	Class IIa	N/A	04232980886
Gas Sampling Line	Class IIa	N/A	04232980886
External Drainage Set	Class IIa	N/A	04232980886
Vent Catheter	Class IIa	N/A	04232980886
Vessel Cannula	Class IIa	N/A	04232980886
Coronary Artery Retraction Clips	Class IIa	N/A	04232980886
Urine Collection Bag	Class Is	N/A	04232980886
Pleural Drainage Set	Class Is	N/A	04232980886
Central Venous Pressure Set	Class Is	N/A	04232980886
Guedel Airway	Class Is	N/A	04232980886
Spigot	Class Is	N/A	04232980886
Extension Lines	Class Is	N/A	04232980886
Kapkon Connector	Class Is	N/A	04232980886
Straight Connector	Class Is	N/A	04232980886
Straight Luer Connector	Class Is	N/A	04232980886
Y Connector	Class Is	N/A	04232980886
Y Luer Connector	Class Is	N/A	04232980886
Stopper	Class Is	N/A	04232980886
Instopper	Class Is	N/A	04232980886
Umbilical Cord Clamp	Class Is	N/A	04232980886
T.U.R. Set /Arthroscopy set	Class Is	N/A	04232980886
Transfer Set	Class Is	N/A	04232980886
Intravenous Infusion Sets	Class Is	N/A	04232980886
Intravenous Infusion Sets / Flowmeter	Class Is	N/A	04232980886
Intravenous Infusion Sets / Burette	Class Is	N/A	04232980886
B -Safe	Class Is	N/A	04232980886
Intubation Stylet	Class Is	N/A	04232980886
Combi Stopper	Class Is	N/A	04232980886
Urimeter	Class Is	N/A	04232980886
Thoracic Drainage Set	Class Is	N/A	04232980886
Vaginal Specula	Class Is	N/A	04232980886
ENEMA Set	Class Is	N/A	04232980886
I.V. Infusion Set w/B-Flow Flow Regulator	Class Is	N/A	04232980886
Control Syringe	Class Is	N/A	04232980886
Meconium Aspiration Connector	Class Is	N/A	04232980886
Urimeter	Class Im	N/A	04232980886
C.V.P. Set	Class Im	N/A	04232980886
Pleural Drainage Set	Class Im	N/A	04232980886
Volumetric Exerciser (B -Spiro)	Class Im	N/A	04232980886
Infusion Set w/Burette	Class Im	N/A	04232980886
Thoracic Drainage Set	Class Im	N/A	04232980886

TÜVNORD

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-07-05	Rev. 0	Initial issue

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

UYGUNLUK DEKLARASYONU
DECLARATION OF CONFORMITY
(Class Is,Im,IIa,IIb,III)
(Sınıf Is,Im,IIa,IIb,III)

Doküman Numarası Document Number	DoC-TK2	**Revizyon No:** 14 Revision No	**Tarih:** 29.12.2016 Date
Üretici Firma Manufacturer	BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş.		
Firma adresi Manufacturer Address	Osmangazi Mahallesi Gazi Caddesi No:21 Esenyurt 34522 İSTANBUL/TÜRKİYE		
Onaylanmış Kuruluş Adres Notified Body Address	TUVNORD CERT GmbH Langemarckstraße 20 45141/Essen-Germany		

BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. Yetkili otorite TÜV NORD (N° 0044) tarafından değerlendirmiştir. Bu deklerasyon, Tıbbi Cihaz Direktifi 93/42 EEC Ek VII ve Düzeltme 2007/47/EEC ile uyumlu olarak hazırlanmıştır.

BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. having been assessed by TÜV NORD Notified Body N° 0044.
This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC and Amendment 2007/47/EEC

Uygunluk deklarasyonunda bulunan bütün ürünler için/For all products which are mentioned in the DoC

Sertifikalar Certificates	**Sertifika No** Certicate No	**Veriliş Tarihi** Date of Issue	**Son Kullanma Tarihi** Expiry Date
EN ISO 13485 (*)	04 221 980886	17.09.2015	16.09.2018
93/42 EEC Ek II / Annex II (4 hariç /without 4)	04 232 980886	30.03.2016	16.09.2018
93/42 EEC Ek II, 4 / Annex II, 3 and 4 (Vent Catheter)	04 231 98088602	20.08.2015	25.01.2020
93/42 EEC Ek II, 4 / Annex II, 3 and 4 (Atrial Cannula)	04 231 98088601	20.08.2015	25.01.2020
93/42 EEC Ek II, 4 / Annex II, 3 and4 (Intercardiac Sump)	04 231 98088604	30.04.2015	25.04.2017
93/42 EEC Ek II, 4 / Annex II, 3 and 4 (Vessel Cannula)	04 231 98088603	14.09.2016	20.05.2020

(*) EN ISO 13485: 2012+AC 2012 Tıbbi Cihazlar- Kalite Yönetim Sistemleri- Ruhsatlandırma Amaçlı Gereklilikler – Teknik Düzeltme 1 (ISO 13485:2003+Cor 1:2009)/ Medical Devices-Quality Management Systems- Requirements for Regulatory Purposes- Technical Corrigendum 1 (ISO 13485:2003+Cor 1:2009)

Bıçakcılar Tıbbi Cihazlar A.Ş, Tıbbi Cihazlar Direktifinin 93/42 EEC ve Ek 2007/47/EEC Ek II maddelerine uygun olarak aşağıda belirtilen ürünler için bütün sorumluluğu üstlenir ve ürünün aşağıda belirtilen standardlara ya da diğer düzenleyici mevzuatlara uygunluğunu deklare eder.
Bıçakcılar Tıbbi Cihazlar A.Ş, Declare under our sole responsibility that the products below to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of Medical Device Directive 93/42 EEC and Amendment 2007/47/EEC Annex II.

Sınıf III Ürünler / *Class III Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** *GMDN Code*	**Sterilite Durumu** *Sterility State*	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** *Device Risk Rule*
1	330 0XXX 1	Vent Kateter Vent Catheter	35891	Steril	NA	Kural 7 Rule 7
2	330 0098 1	Atriyal Kanül Atrial Cannula	17613	Steril	NA	Kural 7 Rule 7
3	330 04XX 1	Intrakardiyak Sump Intracardiac Sump	34923	Steril	NA	Kural 7 Rule 7
4	330 02XX 1	Vessel Kanül Vessel Cannula	47798	Steril	NA	Kural 7 Rule 7

Sınıf IIb Ürünler / *Class IIb Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	157 00XX 1 157 00XX 1G	Lökosit Filtre Seti Leukocyte Filter Set	35071	Steril	ANSI/AAMI BF64:2002 /(R)2007	Kural 3/ Kural 18 Rule 3 /Rule 18
2	040 XXXX 1 400 XXXX 1	Basınç İzleme Seti Pressure Monitoring Set	35529	Steril	NA	Kural 10 Rule 10

Sınıf IIa Ürünler / *Class IIa Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	015 0102 X	Arteriyal İğne Arterial Needle	12747	Steril / Non-Steril	EN 20594-1 (1993)	Kural 6 Rule 6
2	010 2XXX 1 104 1001 1	İnfüzyon pompa seti Infusion pump set	35833	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
3	113 XXXX 1 114 XXXX 1	IV Filtre Seti IV Filter Set	35072	Steril	NA	Kural 3 Rule 3
4	012 XXXX X 123 1XXX 1 123 1XXX 3	Üç yollu musluklu uzatma Extention Line w/three way stopcock	12170	Steril / Non-Steril	NA	Kural 2 Rule 2
5	014 XXXX 1 145 XXXX 1 146 XXXX 1 095 10XX 1	B-CAT I.V Kanül B-CAT I.V Cannula	34920	Steril	EN ISO 10555-1 (2013) EN ISO 10555-5 (1997)	Kural 7 Rule 7

6	015 00XX 1 150 XXXX 1 151 XXXX 1 154 XXXX 1 155 XXXX 1 095 12XX 1	Kan Transfüzyon Seti Blood Transfusion Set	38569	Steril	EN ISO 8536-4 (2013) EN ISO 1135-4 (2012)	Kural 2 Rule 2
7	155 XXXX 1 156 XXXX 1	Mikroagregat Filtre Seti Microaggregate Filter Set	35071	Steril	EN ISO 1135-4 (2012)	Kural 3 Rule 3
8	016 XXXX 1 160 XXXX 1 161 XXXX 1	Yankuer Aspirasyon Ucu Yankuer Suction Handle	35917	Steril	NA	Kural 6 Rule 6
9	162 XXXX 1	Aspiratör ucu Suction wand	35917	Steril	NA	Kural 6 Rule 6
10	016 XXXX X 164 XXXX 1 165 XXXX 1 166 XXXX 1 167 XXXX 1 168 XXXX 1	Yankuer Aspirasyon Seti Yankuer Suction Set	35917	Steril / Non-Steril	NA	Kural 6 Rule 6
11	016 XXXX X 168 XXXX X 169 XXXX 1	Aspirasyon Bağlantı Hortumu Suction Connecting Tube	16779	Steril / Non-Steril	NA	Kural 6 Rule 6
12	017 XXXX 1 171 XXXX X 173 XXXX 1	B-Vak Doku Drenaj Seti B-Vak Wound Drainage Set B-Vak Mini Doku Drenaj Seti B-Vak Mini Wound Drainage Set	35824	Steril / Non-Steril	EN 1617 (1997)	Kural 7 Rule 7
13	018 XXXX X 180 XXXX 1 182 XXXX 1	Toraks Kateteri –Genişleyen Uçlu Thoracic Catheter w/Flared End	11308	Steril / Non-Steril	EN 1617 (1997)	Kural 7 Rule 7
14	018 XXXX X 181 XX01 1 183 XX01 1	Toraks Kateteri Tut Çek Konnektörlü Uç Thoracic Catheter w/Pull Through End	11308	Steril / Non-Steril	EN 1617 (1997)	Kural 7 Rule 7
15	018 XXXX X 184 XXXX 1	Toraks Kateteri Trokarlı Thoracic Catheter w/Throcar	11308	Steril / Non-Steril	EN 1617 (1997)	Kural 7 Rule 7
16	019 XXXX 1 189 XXXX 1	Aspirasyon Kateteri (Kapkon Konnektörlü) Suction Catheter (w/Kapkon connector)	34923	Steril	EN ISO 8836 (2009)	Kural 5 Rule 5
17	019 XXXX 1 190 XXXX 1	Aspirasyon Kateteri Suction Catheter	34923	Steril	EN ISO 8836 (2009)	Kural 5 Rule 5
18	019 XXXX 1 191 XX11 1	Aspirasyon Kateteri-Vakum Kontrollü Suction Catheter w/vacuum control connector	34923	Steril	EN ISO 8836 (2009)	Kural 5 Rule 5
19	019 XXXX 1 193 XXXX 1	Mide Kateteri Stomach Catheter	35415	Steril	EN 1615 (2000)	Kural 5 Rule 5

20	019 XXXX 1 194 XXXX 1	Nazogastrik Kateter Nasogastric Catheter	14221	Steril	EN 1615 (2000)	Kural 5 Rule 5
21	019 XXXX 1 195 XX01 1 195 XX05 1	Nelaton Kateter (Nelaton Catheter) Nelaton Female Kateter (Nelaton Female Catheter)	36125	Steril	EN 1618 (1997) EN 1616 (1997 A1:1999)	Kural 5 Rule 5
22	019 XXXX 1 195 XX20 1	Tiemann Kateteri Tiemann Catheter	36125	Steril	EN 1616 (1997 A1:1999)	Kural 5 Rule 5
23	196 XXXX 1	B-Soft Hidrofilik Kaplı Kateter B-Soft Hydrophilic Coated Catheter	36125	Steril	EN 1616 (1997 A1:1999)	Kural 5 Rule 5
24	196 XX21 1	B-SOFT Kit	36125	Steril	EN 1616 (1997 A1:1999)	Kural 5 Rule 5
25	019 XXXX 1 197 XXXX 1	Beslenme Kateteri Feeding Catheter	14221	Steril	EN 1615 (2000)	Kural 5 Rule 5
26	019 XXXX 1 198 XXXX 1	Göbek Kateteri Umbilical Catheter	10759	Steril	NA	Kural 7 Rule 7
27	019 XXXX 1 199 XXXX 1	Rektal Kateter Rectal Catheter	46202	Steril	EN 12439 (1998)	Kural 5 Rule 5
28	030 XXXX 1 032 XXXX 1 300 XXXX 1 304 XXXX 1 310 XXXX 1 311 XXXX 1 312 XXXX 1 315 XXXX 1	Ekstrakorporeal Tüp Set Extracorporeal Tubing Set	35441	Steril	NA	Kural 2 Rule 2
29	030 XXXX 1 300 XXXX 1 305 XXXX X 306 XXXX X 307 XXXX X	Ekstrakorporeal PVC Hortum Extracorporeal PVC Tubing	46721	Steril / Non-Steril	NA	Kural 2 Rule 2
30	032 XXXX 1 320 XXXX 1	Hızlı Doldurma Seti Quick Prime Set	35441	Steril	NA	Kural 2 Rule 2
31	032 XXXX 1 325 XXXX 1	Kardiopleji Set Cardioplegia Set	16163	Steril	NA	Kural 2 Rule 2
32	323 XXXX 1	Y Adaptör / Perfüzyon Y- Adaptör Y Adapter / Perfusion Y- Adapter	58824	Steril	NA	Kural 2 Rule 2
33	330 03XX 1	Kardiyopleji Adaptörü Cardioplegia Adapter	58824	pSteril	NA	Kural 2 Rule 2

34	330 05XX 1 330 0XXX 1	Turnike set Tourniquet set	36082	Steril	NA	Kural 2 Rule 2
35	340 XXXX 1 341 XXXX 1 135 XXXX 1 138 XXXX 1	Anjiografik Opak Madde Verme Seti Angiographic Kit	16545	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
36	332 XXXX 1	Aortik Punch	47914	Steril	NA	Kural 6 Rule 6
37	042 000X 1 420 XX01 1	Yumuşak Dren Soft Drain	11305	Steril	EN ISO 8669-2 (1996)	Kural 7 Rule 7
38	421 0001 1	Torasentez Seti Thoracentesis Set	11308	Steril	NA	Kural 6 Rule 6
39	042 0001 1 425 0001 1	Göğüs Drenaj Torbası Pleural Drainage Bag	10817	Steril	NA	Kural 7 Rule 7
40	440 4001 1	Arteriyal Filtre Seti Arterial Filter Set	33309	Steril	NA	Kural 2 Rule 2
41	055 XXXX 1 550 XXXX 1 551 XXXX 1	Endotrakeal Tüp Endotracheal Tube	46967	Steril	EN 1782 (1998) EN ISO 5361 (2012)	Kural 5 Rule 5
42	550 XXXX 1 551 XXXX 1	RAE Endotrakeal Tüp RAE Endotracheal Tube	46967	Steril	EN 1782 (1998) EN ISO 5361 (2012)	Kural 5 Rule 5
43	055 XXXX 1 095 22XX 1 550 7XXX 1 551 7XXX 1	Spiralli Endotrakeal Tüp (Balonlu/Balonsuz) Reinforced Endotracheal Tube (Cuffed/Uncuffed)	46569	Steril	EN 1782 (1998) EN ISO 5361 (2012)	Kural 5 Rule 5
44	055 XXXX 1 555 0XXX 1 556 0XXX 1 095 22XX 1	Trakeostomi Tüp Tracheostomy Tube	35404	Steril	EN ISO 5366-1.(2009) EN 1282-2 (2005) (A1:2009)	Kural 5 Rule 5
45	056 200X 2 560 2001 2 560 2002 2 056 2001 2	Nasal Oksijen Kanülü Nasal Oxygen Cannula	35201	Non-Steril	NA	Kural 2 Rule 2
46	056 XXXX 1 563 XXXX 1	Oksijen Kateteri Oxygen Catheter	35203	Steril	NA	Kural 2 Rule 2
47	056 XXXX 1 565 XXXX X	Oksijen Bağlantı Hortumu Oxygen Connecting Tube	12875	Steril / Non-Steril	NA	Kural 2 Rule 2
48	573 0X7X 1 057 0X7X 1 573 0X7X 2 057 0X7X 2	Gaz Örnekleme Hattı Gas Sampling Line	45566	Steril / Non-Steril	NA	Kural 2 Rule 2

49	072 XXXX 1 723 XX70 1 726 XX70 1 724 XXXX 1	Cerrahi Örme Bant Surgical Braided Tape	36082	Steril	NA	Kural 7 Rule 7
50	076 XXXX 1 760 XXXX 1	Üç Yollu Musluk Three Way Stopcock	32172	Steril	NA	Kural 2 Rule 2
51	076 XXXX X 765 XXXX X	Manifold	32172	Steril / Non-Steril	NA	Kural 2 Rule 2
52	079 XXXX 1 790 XX01 1	Redon Dren Redon Drain	11305	Steril	EN 1617 (1997)	Kural 7 Rule 7

Sınıf Im Ürünler / *Class Im Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	186 XXXX 2	B-Spiro Nefes Egzersiz Cihazı B-Spiro Volumetric Exerciser	31266	Non-Steril	NA	Kural 5 Rule 5

Sınıf Is Ürünler / *Class Is Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	010 XXXX 1 100 XXXX 1 101 XXXX 1 102 XXXX 1 103 XXXX 1	I.V. İnfüzyon Seti I. V. Infusion Set	58977	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
2	010 05XX 1 106 000X 1 107 000X 1	İnfüzyon Seti-Damla Ayarlı I.V. Infusion Set w/Flowmeter	58977	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
3	012 XXXX 1 120 XXXX 1 121 XXXX 1 122 XXXX 1	Uzatma Hatları Extention Lines	12170	Steril	NA	Kural 2 Rule 2
4	012 XXXX 1 125 0005 1 125 0001 1	Stoper / Instoper	31667	Steril	EN 20594-1 (1993) (AC:1996) (A1:1997) ISO 594-2 (1998)	Kural 2 Rule 2
5	012 XXXX 1 125 0007 1	Kombi Stoper Combi stopper	31667	Steril	NA	Kural 2 Rule 2
6	012 XXXX 1 125 0010 1	Transfer Set	41222	Steril	NA	Kural 1 Rule 1
7	012 XXXX 1 125 10XX 1 130 XXXX 1 131 XXXX 1	B Safe	42727	Steril	NA	Kural 2 Rule 2
8	131 00XX 1 132 00XX 1 133 XXXX 1 124 XXXX 1	B Safe Valfli Uzatma-İkili/Üçlü Extension Line w/B-Safe Duo/Triple/T-Connector	12170	Steril	NA	Kural 2 Rule 2

9	013 80XX 1 135 XXXX 1 138 XXXX 1	Basınca Dayanıklı Uzatma Hatları Pressure Extention Lines	16621	Steril	NA	Kural 2 Rule 2
10	022 XXXX 1 228 XXXX 1	Lavman Seti (Enema Set) Lavman Torba (Enema Bag)	35050	Steril	NA	Kural 5 Rule 5
11	023 0001 1 230 0001 1	Göbek Kordon Klempi Umbilical Cord Clamp	43998	Steril	NA	Kural 1 Rule 1
12	023 0001 1 235 0001 1	Konik Konnektör Conical Connector	44545	Steril	NA	Kural 1 Rule 1
13	023 0001 1 236 XXXX 1	Hortum Konnektörü Tubing Connector	44545	Steril	NA	Kural 2 Rule 2
14	023 XXXX 1 238 0001 1 238 0011 1	Kateter Tıkacı Spigot	31667	Steril	NA	Kural 1 Rule 1
15	024 0001 1 240 0001 1	Kapkon Konnektör Kapkon Connector	44545	Steril	EN ISO 8836 (2009)	Kural 1 Rule 1
16	043 XXX1 1 430 XXXX 1	TUR Set	46102	Steril	NA	Kural 2 Rule 2
17	045 XXXX 1 450 XXX1 1	Artroskopi Set Arthroscopy Set	46102	Steril	NA	Kural 2 Rule 2
18	055 XXXX 1 550 000X 1	Entübasyon Stile Entubation Stylet	37469	Steril	NA	Kural 5 Rule 5
19	595 10XX 1	Vajinal Spekulum Vaginal Specula	37468	Steril	TS 5537:1988 AC 2003	Kural 5 Rule 5
20	075 XXXX 1 750 XXXX 1	Düz Konnektör Straight Connector	35338	Steril	NA	Kural 2 Rule 2
21	075 XXXX 1 751 XXXX 1	Düz Luer Konnektör Straight Luer Connector	35338	Steril	NA	Kural 2 Rule 2
22	075 XXXX 1 754 XXXX 1	Y Konnektör Y Connector	35338	Steril	NA	Kural 2 Rule 2
23	075 XXXX 1 755 XXXX 1	Y Luer Konnektör Y Luer Connector	35338	Steril	NA	Kural 2 Rule 2
24	090 XXXX 1 900 XXXX 1 095 90XX 1	Guedel Havayolu Guedel Airway	42424	Steril	EN ISO 12181 (2011) EN ISO 5364 (2011)	Kural 2 Rule 2
25	034 XXXX 1	Kontrol Şırıngası Control Syringe	15286	Steril	NA	Kural 2 Rule 2
26	106 XXXX 1 107 000X 1	Damla Ayar Seti Flow Regulator	36244	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
27	022 XXXX 1 222 XXXX 1 223 XXXX 1 226 XXXX 1	İdrar Torbası Urine Collection Bag	58921 58922	Steril	EN ISO 8669-2 (1996)	Kural 1 Rule 1
28	022 XXXX 1	Bacak İdrar Torbası Leg Bag	58924	Steril	NA	Kural 1 Rule 1
29	236 1001 1	Mekonyum Aspiratör Konnektörü Meconium Aspirator Connector	35400	Steril	NA	Kural 2 Rule 2

Sınıf Is-Im Ürünler / *Class Is & Im Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	010 XXXX 1 105 XXXX 1 095 11XX 1	I.V. Infüzyon Seti-Büretli I.V. Infusion Set-w/Burette	12159	Steril	EN ISO 8536-5 (2013)	Kural 2 Rule 2
2	011 XXXX 1 110 0001 1	C. V. P. SET Central Venous Pressure Monitoring Set	35529	Steril	EN ISO 8536-4 (2013)	Kural 2 Rule 2
3	017 XXXX 1 175 XXXX 1	BPDS- Göğüs drenaj seti Pleural Drainage Set	10817	Steril	EN 1617 (1997)	Kural 1 Rule 1
4	017 XXXX 1 176 200X 1	BTDS –Toraks drenaj seti Thoracic Drainage Set	10817	Steril	EN 1617 (1997)	Kural 1 Rule 1
5	227 XXXX 1 022 XXXX 1	Ürimetre Urimeter	32072	Steril	EN ISO 8669-2 (1996)	Kural 1 Rule 1
6	022 7XXX 1 227 10XX 1	Urimetre İdrar Torbalı Urimeter w/Urine BAG	32072	Steril	EN ISO 8669-2 (1996)	Kural 1 Rule 1

Açıklama: XXXX ürünün farklı uzunluk, ölçü gibi farklılıklarını ifade etmektedir./
Explanation:XXXX means different length, sizes etc. product.

NA: İlgili ürün standardı bulunmamaktadır./ **There is no related product standard.**

ONAY / APPROVAL	
Yayın Yeri ve İmza Tarihi **Signature Date and Place of Issue**	
Yetkili kişinin adı, ünvanı, imzası ve firma kaşesi **Name, title, signature of authorized person with company cachet**	
Kalite Sistem Belgelendirme Yöneticisi **Quality System Certification Manager**	Kalite ve Laboratuvar Müdürü **Quality and Laboratory Manager**
	Ülkü ÖKER
	2017

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Manufacturer: CAIR LGL

Address:
1 Allée Des Chevreuils
Lissieu
69380
France

Single Registration Number: FR-MF-000007921

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

& Quality

First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Enteral feeding, drug administration/ Enteral suction devices and accessories	Class IIa

First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3566773	Issued

First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

By Royal Charter

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761075 R000

Manufacturer: CAIR LGL

Address:
1 Allée Des Chevreuils
Lissieu
69380
France

Single Registration Number: FR-MF-000007921

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761075 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Suction and dilatation systems for the respiratory system	Class Is
Drainage and fluid collection devices	Class Is
Intubation devices and accessories	Class Is
Respiratory masks, and balloons and accessories	Class Is
Oxygen administration and humidification systems	Class Is
Tubular devices	Class Im / Class Is
Samples collection devices – various	Class Is
Syringes accessories	Class Is
Adapters, connectors, ramps, stopcocks, caps	Class Is
Newborn nutrition devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761075 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-09-25	3566773	Issued
Current	30152906	Supplemented – Addition of Class Is devices

First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 078540 0013 Rev. 00

Manufacturer:

Changzhou Standard Medical Devices Co., Ltd.
Tongjiang Road
Xinbei District
213022 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018989

Authorized Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 078540 0013 Rev. 00

Report No.: SH2270202

Valid from: 2023-05-16
Valid until: 2028-05-15

Issue date: 2023-05-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 078540 0013 Rev. 00

Classification:	Class I
Device Group:	A06030301 - URINE COLLECTION BAGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A06030302 - HOURLY DIURESIS MEASUREMENT SETS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report	Description
00	2023-05-16	SH2270202	Initial issuance

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®

3EC®
international

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.

Notified body

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

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

In Bratislava, Slovakia, 30.09.2022

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

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	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

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 1ml with needle 0,5 x 16 mm and filter 2ml with needle 0,45 x 12 mm and filter 2ml with needle 0,5 x 16 mm and filter	10100 10200 10300 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

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 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

Notified body 3EC international NB 2265 NOTIFIKOVANÁ

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 Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	**CHIRANA**	1ml 31G x 5/16"U100 0,5ml 29G x 1/2"U100 0,5ml 30G x 1/2"U100 0,5ml 30G x 5/16"U100 0,5ml 31G x 5/16"U100 0,5ml 31G x 4/16"U100 0,3ml 29G x 1/2"U100 0,3ml 30G x 1/2"U100 0,3ml 31G x 5/16"U100 0,3ml 31G x 4/16"U100	CHINS01318PB CHINS00529PB CHINS00530PB CHINS005308PB CHINS005318PB CHINS005316PB CHINS00329PB CHINS00330PB CHINS003318PB CHINS003316PB
Sterile Tubercilin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	**CHIRANA**	1 ml Luer 1ml 29G x 1/2"	CHTUB01 CHTUB0129

Notified body NB 22 NOTIFIKOVA

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 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

Notified body · 3E International · NB 22 · NOTIFIKOVANÁ

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 Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	**HARMOFINE**	1ml 31G x 5/16"U100 0,5ml 29G x 1/2"U100 0,5ml 30G x 1/2"U100 0,5ml 30G x 5/16"U100 0,5ml 31G x 5/16"U100 0,5ml 31G x 4/16"U100 0,3ml 29G x 1/2"U100 0,3ml 30G x 1/2"U100 0,3ml 31G x 5/16"U100 0,3ml 31G x 4/16"U100	HFINS01318PB HFINS00529PB HFINS00530PB HFINS005308PB HFINS005318PB HFINS005316PB HFINS00329PB HFINS00330PB HFINS003318PB 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			

Notified body

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	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

Notified body NB 22 NOTIFIKOVANÁ OSO

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

Notified body

NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-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 · NB 2265 · NOTIFIKOVANÁ

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

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2022-MDR/QS-025

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 Needles 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.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

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-025

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 Needle for Single Use	MEDOJECT	0.3x12mm	CH30012
		0.3x25mm	CH30100
		0.3x40mm	CH30112
		0.33x12mm	CH29012
		0.33x25mm	CH29100
		0.33x40mm	CH29112
		0.4x12mm	CH27012
		0.4x16mm	CH27058
		0.4x20mm	CH27034, CH27045
		0.4x40mm	CH27112
		0.45x12mm	CH26012
		0.45x16mm	CH26058
		0.45x20mm	CH26045
		0.45x25mm	CH26100
		0.45x40mm	CH26112
		0.5x16mm	CH25058
		0.5x20mm	CH25045
		0.5x25mm	CH25100
		0.5x40mm	CH25112
		0.5x42mm	CH25158
		0.5x60mm	CH25214
		0.55x25mm	CH24100
		0.55x38mm	CH24112
		0.55x40mm	CH24112
		0.6x16mm	CH23058
		0.6x25mm	CH23100
		0.6x30mm	CH23114
		0.6x40mm	CH23112
		0.6x60mm	CH23214
		0.6x80mm	CH23318

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-025

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 Needle for Single Use	MEDOJECT	0.7x30mm	CH22114
		0.7x35mm	CH22125
		0.7x40mm	CH22112
		0.7x50mm	CH22200
		0.7x90mm	CH22358
		0.8x16mm	CH21058
		0.8x25mm	CH21100
		0.8x30mm	CH21114
		0.8x40mm	CH21112
		0.8x50mm	CH21200
		0.8x100mm	CH21400
		0.8x120mm	CH21434
		0.9x25mm	CH20100
		0.9x30mm	CH20114
		0.9x38mm	CH20112
		0.9x40mm	CH20112
		0.9x50mm	CH20200
		0.9x70mm	CH20245
		1.1x25mm	CH19100
		1.1x30mm	CH19114
		1.1x40mm	CH19112
		1.1x50mm	CH19200
		1.2x25mm	CH18100
		1.2x38mm	CH18112
		1.2x40mm	CH18112
		1.2x50mm	CH18200
		1.2x70mm	CH18245
		1.2x100mm	CH18400
		1.5x50mm	CH17200
		1.5x100mm	CH17400

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-025

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 Needle for Single Use	MEDOJECT	1.6x15mm	CH16058
		1.6x25mm	CH16100
		1.6x35mm	CH16125
		1.6x40mm	CH16112
		1.6x70mm	CH16245
		1.6x110mm	CH16438
		1.8x30mm	CH15114
		1.8x40mm	CH15112
		1.8x70mm	CH15245
		1.8x110mm	CH15438
		2.0x30mm	CH14114
		2.0x70mm	CH14245
		2.0x80mm	CH14318
		2.0x100mm	CH14400
		2.0x120mm	CH14434
		2.1x40mm	CH14112
		2.1x120mm	CH14434

Product	Trade Name	Models	REF code
Sterile Ophthalmic Needle for Single Use	INOX – Straight	0.4x20mm	CHOP27045S
		0.4x25mm	CHOP27100S
		0.5x20mm	CHOP25045S
		0.5x25mm	CHOP25100S
		0.6x20mm	CHOP23045S
Sterile Ophthalmic Needle for Single Use	INOX – Bent	0.4x20mm	CHOP27045B
		0.5x22mm	CHOP25045B
		0.6x20mm	CHOP23045B
		0.6x22mm	CHOP23045B

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-025

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
Blood Collection Needle for Single Use	CHIRAVAC™	23G x 1" (0.6 x 25mm)	CHBCN23100
		23G x 1 1/2" (0.6 x 38mm)	CHBCN23112
		22G x 1" (0.7 x 25mm)	CHBCN22100
		22G x 1 1/2" (0.7 x 38mm)	CHBCN22112
		21G x 1" (0.8 x 25mm)	CHBCN21100
		21G x 1 1/2" (0.8 x 38mm)	CHBCN21112
		20G x 1" (0.9 x 25mm)	CHBCN20100
		20G x 1 1/2" (0.9 x 38mm)	CHBCN20112
		18G x 1" (1.2 x 25mm)	CHBCN18100
		18G x 1 1/2" (1.2 x 38mm)	CHBCN18112
Blood Collection Needle for Single Use	TECROM	23G x 1" (0.6 x 25mm)	TCBCN23100
		23G x 1 1/2" (0.6 x 38mm)	TCBCN23112
		22G x 1" (0.7 x 25mm)	TCBCN22100
		22G x 1 1/2" (0.7 x 38mm)	TCBCN22112
		21G x 1" (0.8 x 25mm)	TCBCN21100
		21G x 1 1/2" (0.8 x 38mm)	TCBCN21112
		20G x 1" (0.9 x 25mm)	TCBCN20100
		20G x 1 1/2" (0.9 x 38mm)	TCBCN20112
		18G x 1" (1.2 x 25mm)	TCBCN18100
		18G x 1 1/2" (1.2 x 38mm)	TCBCN18112

Notified body 3EC international NB 2265 NOTIFIKOVANÁ

Katarina Tomin Srgosova, 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-025

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
Insulin Pen Needle for Single Use	MEDOJECTfine	29G x 10 mm	CHPN2910
		29G x 12,7 mm	CHPN29127
		30G x 6 mm	CHPN3006
		30G x 8 mm	CHPN3008
		31G x 4 mm	CHPN3104
		31G x 5 mm	CHPN3105
		31G x 6 mm	CHPN3106
		31G x 8 mm	CHPN3108
		32G x 4 mm	CHPN3204
		32G x 5 mm	CHPN3205
		32G x 6 mm	CHPN3206
		32G x 8 mm	CHPN3208
		33G x 4 mm	CHPN3304
Insulin Pen Needle for Single Use	HARMOFINE®	29G x 10 mm	HFPN2910
		29G x 12,7 mm	HFPN29127
		30G x 6 mm	HFPN3006
		30G x 8 mm	HFPN3008
		31G x 4 mm	HFPN3104
		31G x 5 mm	HFPN3105
		31G x 6 mm	HFPN3106
		31G x 8 mm	HFPN3108
		32G x 4 mm	HFPN3204
		32G x 5 mm	HFPN3205
		32G x 6 mm	HFPN3206
		33G x 4 mm	HFPN3304
Insulin Pen Needle for Single Use	DIABFINE	31G x 5 mm	DBF531
		31G x 8 mm	DBF831
		32G x 4 mm	DBF432

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-025

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
Insulin Pen Needle for Single Use	cleanFINE	31G x 4 mm	A067040TREN-TR01X
		31G x 5 mm	A067050TREN-TR01X
		31G x 6 mm	A067060TREN-TR01X
		31G x 8 mm	A067080TREN-TR01X
Insulin Pen Needle for Single Use	cleanFINE penta	31G x 4 mm	A068040DEEN-XX00X
		31G x 6 mm	A068060DEEN-XX00X
		31G x 8 mm	A068080DEEN-XX00X

Product	Trade Name	Models	REF code
Scalp Vein Set for Single Use	CHIRAFLEX	18G	CH260001118
		19G	CH260001119
		20G	CH260001120
		21G	CH260001121
		22G	CH260001122
		23G	CH260001123
		24G	CH260001124
		25G	CH260001125
		26G	CH260001126
		27G	CH260001127

Product	Trade Name	Models	REF code
Sterile Safety Hypodermic Needle for Single Use	MEDOJECT	0,6x30mm (23G x 1 1/4")	CHS23114
		0,7x40mm (22G x 1 1/2")	CHS22112
		0,8x40mm (21G x 1 1/2")	CHS21112
		0,9x40mm (20G x 1 1/2")	CHS20112

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[redacted]

Katarína Tomin Grošová, 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-025

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 Needle for Single Use: MEDOJECT - injection and taking off a blood and other liquids at patients

Sterile Ophthalmic Needle for Single Use: INOX (Straight, Bent) - administration of fluids in the eye (ocular irrigation canals) patients

Blood Collection Needle for Single Use: CHIRAVAC™ / TECROM - blood collection in connection with blood collection tube

Insulin Pen Needle for Single Use: MEDOJECTfine / HARMOFINE® / DIABFINE / cleanFINE / cleanFINE penta - delivery of insulin in conjunction with injection pens

Scalp Vein Set for Single Use: CHIRAFLEX - access into the peripheral vascular system for administration of fluids and drugs and for withdrawal of blood at patient

Sterile Safety Hypodermic Needle for Single Use: MEDOJECT - injection and taking off a blood and other liquids at patients

Notified body
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-025

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-025	30.09.2022	MDR077_2022, MDR100_2022, MDR101_2022, MDR104_2022, MDR110_2022 MDR112_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

3EC®
international

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2022-MDR/QS-024

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, Non-Implantable Medical devices: Sterile Medical Devices for Administration, Withdrawal and Collection
(For detailed list refer to Annex I)

Intended purpose: See Annex II
MD class Is

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**

For class Is devices, the audit by the NB2265 of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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 Audit Report No. SK-0655/22 from 21.09.2022. Information on all examinations and tests performed is stated in the abovementioned report 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-024

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:

Syringes

Product	Trade Name	Models	REF code
Sterile Irrigation Syringe for Single Use	CHIRANA	50ml catheter 50ml catheter + Luer adapter 100 ml catheter + Luer adapter 150ml JANETTE 150ml JANETTE + Luer adapter	CH03050C CH03050CLA CH03100C CH03150CS CH03150CSLA
Sterile Irrigation Syringe for Single Use	CATHETER TIP SYRINGE	50ml catheter tip syringe 50ml catheter tip syringe + adapter	22008 22011

Syringes

Product	Trade Name	Models	REF code
Sterile Enteral Syringe for Single Use	CHIRANA	20ml 60ml	CH03020E CH03060E

Solution Filters

Product	Trade Name	Models	REF code
Spike for Single Use	CHIRAPLUS	Infusion spike RED Infusion spike BLUE Infusion spike GREEN	CHIS01 CHIS02 CHIS03

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

[redacted]

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-024

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:

Solution Filters

Product	Trade Name	Models	REF code
Sterile filter for single use	SYRIFILT	N/A	10500
Sterile filter for single use	STERIFILT	N/A	AP02-001-00
Sterile filter for single use	STERI5	N/A	AP02-003-00

Needles

Product	Trade Name	Models	REF code
Sterile Blunt Fill Needle for Single Use	MEDOJECT	1,2x40mm (18G x 1 1/2") 1,2x50mm (18G x 2") 1,2x40mm with filter (18G x 1 1/2") 1,2x50mm with filter (18G x 2")	CH18112BF CH18200BF CH18112F CH18200F

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdosova, 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-024

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 Irrigation Syringe for Single Use: CHIRANA / CATHETER TIP SYRINGE - rinsing body cavities, washing a patient body and withdrawing body fluids, it can be used to deliver liquid food

Sterile filter for single use: SYRIFILT / STERIFLIT / STERI5 - filtering of impurities during suction of solution into syringe

Spike for Single Use: CHIRAPLUS - pharmaceutical preparations – transmit fluids from one container to another (e.g., transfer medication from the vial to the syringe or from the syringe to the vial), mixing fluids or dissolve dry substances in the vials

Sterile Enteral Syringe for Single Use: CHIRANA - food or drug application via syringe pumps

Sterile Blunt Fill Needle for Single Use: MEDOJECT - to be attached to a syringe in order to aspiration fluids from vials or ampules during the preparation of medications

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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-024

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-024	30.09.2022	MDR097_2022, MDR102_2022, MDR113_2022, MDR116_2022, MDR117_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

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

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

CHIRANA T. Injecta, a.s.

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

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

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

Intended purpose: See Annex II
MD class IIa

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

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

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

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

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

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

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 30.09.2022

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

issued for the company

CHIRANA T. Injecta, a.s.

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

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

Tubular Devices

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

Versions:

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

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

[redacted], PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

issued for the company

CHIRANA T. Injecta, a.s.

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

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

Tubular Devices

Product	Trade Name	Models	REF code
Transfusion Set for Single Use	**CHIRAHEM**	CHIRAHEM	CHT314
		CHIRAHEM	CHT315
		CHIRAHEM	CHT320
		CHIRAHEM	CHT323
		CHIRAHEM with needle	CHT321
		CHIRAHEM with metal spike	CHT322
		CHIRAHEM DEHP Free	CHT514
		CHIRAHEM DEHP Free	CHT515
		CHIRAHEM DEHP Free	CHT516
		CHIRAHEM DEHP Free	CHT517
		CHIRAHEM DEHP Free	CHT518
Versions: - with blood filter - with and without air ventil - with or without flow regulator - with or without needle - Luer / Luer-Lock with cap - with or without flashball - with or without DEHP			

Tubular Devices

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

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

issued for the company

CHIRANA T. Injecta, a.s.

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

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

Adapters, Connectors, Ramps, Stopcock, Caps

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

Adapters, Connectors, Ramps, Stopcock, Caps

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

Adapters, Connectors, Ramps, Stopcock, Caps

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

Adapters, Connectors, Ramps, Stopcock, Caps

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

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027