CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-831

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

AMEDUS MEDİKAL UYGULAMALAR SAĞLIK SANAYİ VE TİCARET LTD. ŞTİ.

Ostim Organize Sanayi Bölgesi Mahallesi 100. Yıl Bulvarı No: 99/34
Yenimahalle / Ankara, Turkey

Product: Topical Vacuum Treatment Device
Types: Careoxi, Topivac
Model Number: Hand T-NPWT, Hand T-NPWT Irrigation, MEDIUM (V1, V2, V3, Clinic V4), TOPI T-NPWT Classic A100, TOPI T-NPWT İncision A200
Product: Topical Vacuum Treatment Set
Types: Careoxi, Topivac
Model Number: Topiset, Multidress, Multicase, Canister, Ozon Bag
Product: Canister Collecting Unit
Types: Careoxi, Topivac
Topivac Models: TPVCA1000, TOPIVAC TPVCA1000, TOPISET TPVCA1000, MULTIDRESS TPVCA1000, TPVCA500, TOPIVAC TPVCA500, TOPISET TPVCA500, MULTIDRESS TPVCA500, CANISTER 1000ml, CANISTER 75ml
Careoxi Models: CTPVCA1000, CAREOXI CTPVCA1000, TOPISET CTPVCA1000, MULTIDRESS CTPVCA1000, CTPVCA500, CAREOXI CTPVCA500, TOPISET CTPVCA500, MULTIDRESS CTPVCA500, CANISTER 1000ml, CANISTER 75ml

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.6151.01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II.

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

Muhteşem Gökhan Yücel
Head of Notified Body

22 May 2021, Istanbul, Turkey

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.
I.T.O.S.B 9. Cadde No: 15
Tepeören Mevkii PK 34959
Tuzla İstanbul
Türkiye

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Notified Body Confirmation Letter

Subject/*Konu* : Extension of MDD Certificate
MDD Sertifikasının Uzatılması

Date/*Tarih*: 29.04.2024

Reference No/*Referans Numarası*: MY-24-002808

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 S.P.A** 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: CERBO0694823** 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 S.P.A** 'ın, 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: CERBO0694823** yazılı anlaşmayı aşağıdaki üretici ile gerçekleştirdiğini teyit etmektedir.*

Amedus Medikal Uygulamalar Sağlık Sanayi Ve Ticaret Limited Şirketi
Ostim Organize Sanayi Bölgesi Mahallesi 100.Yıl Bulvarı No 99/34 Yenimahalle Ankara,
Türkiye

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 **12.03.2024**, an application was submitted to our organization for the extension of the MDD certificate of the products specified in Annex-I. In this context, the company's MDD extension responsibility falls on **Kiwa Belgelendirme Hizmetleri A.Ş.** It will be continued until **26.09.2024.**

***12.03.2024** tarihinde, **Ek-I'de** belirtilen ürünlerin MDD sertifikasnın uzatımı için kuruluşumuza başvuruda bulunulmuştur. Bu bağlamda, şirketin MDD uzatma sorumluluğu 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.	– Topical Vacuum Treatment Device / *Topikal Vakum Tedavi Cihazı* – Topical Vacuum Treatment Set / *Topikal Vakum Tedavi Seti* – Canister Collecting Unit / *Canister Toplama Kabı*	1984-MDD-21-831	27.05.2024	93/42/EEC

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

KİWA
BELGELENDİRME HİZMETLERİ A.Ş.
Eski Ankara Asfalt/İstanbul Tuzla Org. San. Bölg.
9. Cad. No: 15 Tuzla Gebze/ Tuzla/ İSTANBUL/ TÜRKİYE
Tuzla V.D. 620 053 0414 Ticaret Sic. No:365270
MERSIS No: 0620005341700019

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/03/06
CL1/V4

Esteemed

AMEDUS MEDİKAL UYGULAMALAR SAĞLIK SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Ostim Organize Sanayi Bölgesi Mahallesi 100. Yıl Bulvarı No:99/34 Yenimahalle / Ankara, Türkiye

Notified Body Confirmation Letter Reference: CERBO0694823

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, Kiwa Cermet Italy, 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 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

AMEDUS MEDİKAL UYGULAMALAR SAĞLIK SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Ostim Organize Sanayi Bölgesi Mahallesi 100. Yıl Bulvarı No:99/34 Yenimahalle / Ankara, Türkiye

SRN Number (if available): TR-MF-000016889

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,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 07/03/2024 16:34:37

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
-	-	-	-

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
TOPICAL VACUUM TREATMENT DEVICE	Class IIa	Identification of the corresponding device under MDD ✓ Same ☐ Substitute	Certificate No: 1984-MDD-21-831 NB# 1984
TOPICAL VACUUM TREATMENT SET	Class IIb excluding Class IIb implantable non-WET	Identification of the corresponding device under MDD ✓ Same ☐ Substitute	Certificate No: 1984-MDD-21-831 NB# 1984
CANISTER COLLECTING UNIT	Class I devices with a measuring function	Identification of the corresponding device under MDD ✓ Same ☐ Substitute	Certificate No: 1984-MDD-21-831 NB# 1984

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/06	Rev.00	Initial issue: TOPICAL VACUUM TREATMENT DEVICE, TOPICAL VACUUM TREATMENT SET, CANISTER COLLECTING UNIT

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111