Declaration of conformity
Ultrasonic Nebulizer

Document number	:	TD.6.2
Release date	:	03.01.18
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Page	:	1/ 1

Producer : Kare Medical and Analytical Devices Ltd. Company

Head Office Address : Kültür mh. Ziya Gokalp Cd. 36/23 Çankaya / Ankara

Factory Address : Alcı OSB mh. 2017. CD. No: 24 Sincan / Ankara

Product Type : Nebulizer, Ultrasonic

Name of the product : Hikoneb 906 S/Lcd
Hikoneb 908 DC

Class : IIa Rule 11

GMDN Number : 12719

Conformity Assessment Procedure: Annex II.3

Applicable Standards :

TS EN ISO	13485	:2016
TS ISO	27427	:2019
ISO	80601-2-74	:2017
TS EN ISO	14971	:2019
TS EN	60601-1	:2009
TS EN	60601-1-2	:2016
TS EN	60601-1-8	:2008
TS EN	62366-1	:2015
TS ISO	62304/A1	:2016
TS EN ISO	18562-1	:2020
TS EN ISO	20417	:2021
TS EN ISO	15223-1	:2016

Notified Body : Kiwa Belgelendirme Hizmetleri A.Ş.
İtosb 9. cd. Nu:15 Tepeören Tuzla/İstanbul/Türkiye
tel: +90 216 593 2575
www.kiwa.com.tr posta@kiwa.com.tr

Identification No : 1984

EC Certificate : 1984- MDD-18-481 rev:2 14.12.2020

Certificate Release Date : 12.01.2018

Certificate Expiry Date : 27.05.2024

We, Kare Medical and Analytical Devices Ltd. Company declare that the Ultrasonic Nebulizers fully comply with the essential safety and health requirements of the MDD 93/42 / EEC medical device directive (including 2007/47 / EC). Prepared Technical File and documents are under our responsibility. Our devices are not Life Support, Patient Monitoring devices or Sterile. It does not contain human blood and its derivatives, animal tissue, drugs and pharmaceutical ingredients.

Çağlar Yavaş
Company Director
31.05.22- Ankara

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/05/08
CL1/V4a

Esteemed

KARE MEDİKAL VE ANALİTİK CİHAZLAR LTD. ŞTİ

Legal: ZİYA GÖKALP CD. 36/23 ÇANKAYA / ANKARA

OPERATIONAL: ALCI OSB MH. 2017. CD. NO:24 SİNCAN/ANKARA/TÜRKİYE

Notified Body Confirmation Letter Reference: CERBO0183024

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

KARE MEDİKAL VE ANALİTİK CİHAZLAR LTD. ŞTİ

Legal: ZİYA GÖKALP CD. 36/23 ÇANKAYA / ANKARA

OPERATIONAL: ALCI OSB MH. 2017. CD. NO:24 SİNCAN/ANKARA/TÜRKİYESRN Number (if available): TR-MF-000020956

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

NB 0476

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
PAP THERAPY SYSTEMS **(CPAP/AutoCPAP 869893452PC8J Heated Humidifire 869893452PH8U Another devices are BPAP 869893452PB8G)**	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984
PORTABLE SUCTION UNIT (869893452SU9X)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984
COMPRESSOR NEBULIZER (869893452CN7Z)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984
OXYGEN CONCENTRATOR (869893452OC8F)	Class IIb excluding Class IIb implantable non-WET	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984
ULTRASONIC NEBULIZER (869893452VN9S)	Class IIb excluding Class IIb implantable non-WET	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984
VENTILATOR (869893452UN9P)	Class IIb excluding Class IIb implantable non-WET	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-18-481 NB#1984

NBOG

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/08	Rev.00	Initial issue

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

NB 0476

KARE MEDİKAL
Ziya Gökalp Cd. 36/23 Yenişehir-Ankara, 06420
Telefon: 444 52 73 • Fax: (312) 435 83 08

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.
Manufacturer address and contact details	HEAD OFFICE: ZİYA GÖKALP CD. 36/23 YENİŞEHİR ÇANKAYA / ANKARA /TÜRKİYE +90 312 911 4 911 FACTORY: ALCI OSB MH. 2017. CD. NO:24 SİNCAN / ANKARA / TÜRKİYE +90 312 911 4 911
Single Registration Number (SRN) (if available)	TR-MF-000020956

Authorised Representative name (if applicable)	NO
Authorised Representative address and contact details	NO
Single Registration Number (SRN) (if available)	NO

Notified body name (if applicable)	KIWA BELGELENDİRME HİZMETLERİ A. Ş.
Notified body number (if applicable)	1984
Directive Certificate number(s) to which this confirmation is made (if applicable)	1984-MDD-18-481
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27/05/2024
End date of extended validity/transition period	31/12/2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Choose applicable statements:

☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:
- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:
- ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

KARE MEDİKAL
Ziya Gökalp Cd. 36/23 Yenişehir-Ankara, 06420
Telefon: 444 52 73 • Fax: (312) 435 83 08

Signed for and on behalf of the manufacturer:

Full Company Name	KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.
Location & Date	ANKARA / 13/05/2024
Signature, Print Name, Title	ÇAĞLAR YAVAŞ, COMPANY DIRECTOR

KARE MEDİKAL VE ANALİTİK CİHAZLAR SAN. VE TİC. LTD. ŞTİ.
Kültür Mah. Ziya Gökalp Cad. [illegible]
Tel: 0312 811 4 911 iletisim@kare-ltd.com
Mithatpaşa V.D. 524 039 2797 Mersis No: 0524039279700019

Contact Details (at least email) caglar.yavas@kare-ltd.com, kalite@kare-ltd.com

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SEE BELOW	**1984-MDD-18-481**	**27/05/2024**	**KIWA BELGELENDİRME HİZMETLERİ A.Ş. 1984**	**KIWA CERMET ITALIA S.P.A 0476**	**31/12/2028**	**NO**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

KARE MEDİKAL
Ziya Gökalp Cd. 36/23 Yenişehir-Ankara, 06420
Telefon: 444 52 73 • Fax: (312) 435 83 08

Identification of the device(s)[4]
(e.g., device name, family/group name device model or catalogue number)

DEVICE GROUP	DEVICE	UDI-DI
PAP THERAPY SYSTEMS	Sleepone Cpap	08698934521399
	Sleepone Auto Cpap	08698934521405
	Sleepone Bilevel S	08698934521443
	Sleepone Bilevel ST	08698934521450
	Sleepone Bilevel Auto	08698934521467
	Sleepone Bilevel ST Auto	08698934521528
	Sleepone Pro SV	08698934521535
	Sleepone Pro VT	08698934521580
	Sleepone Heated Humidifier	08698934522013
PORTABLE SUCTION UNIT	Ecoaspir	08698934521368
	Ecoaspir Plus	08698934520675
COMPRESSOR NEBULIZER	Hikoneb AeroCare II	08698934520705
	Hikoneb A 103	08698934522020
OXYGEN CONCENTRATOR	Hikoneb Oxybreath 10L	08698934521559
	Hikoneb Oxybreath Mini 5	08698934521474
	Hikoneb Oxybreath Mini 3	08698934521481
VENTILATOR	KMV5010	08698934520057
ULTRASONIC NEBULIZER	Hikoneb 906 S/LCD	08698934520989
	Hikoneb 908 DC	08698934520972

[4] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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

Tel. +90 216 593 25 75
Faks +90 216 593 25 74
posta@kiwa.com.tr
www.kiwa.com
www.1kiwa.com

Notified Body Confirmation Letter

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

Date/*Tarih*: 11.05.2024

Reference No/*Referans Numarası*: MY-24-002847

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: CERBO0183024** 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: CERBO0183024** yazılı anlaşmayı aşağıdaki üretici ile gerçekleştirdiğini teyit etmektedir.*

KARE MEDİKAL VE ANALİTİK CİHAZLAR LTD. ŞTİ
Legal/*Merkez*: ZiyaGökalp cd. 36/23 Yenişehir/Çankaya/Ankara/Türkiye
Operational/*Fabrika*: Ankara II. Osb Alcı osb mh. 2017. Cd. No: 24 Sincan/Ankara

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 **30.04.2024**, 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**.

***30.04.2024** 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.	– Pap Therapy Systems/ *Pap Terapi Sistemleri* – Portable Suction Unit/ *Taşınabilir Aspiratörleri* – Compressor Nebulizer/ *Kompresörlü Nebulizerler* – Oxygen Concentrator/ *Oksijen Konsantratörleri* – Ultrasonic Nebulizer/ *Ultrasonik Nebulizerler* – Ventilator/ *Ventilatörler*	1984-MDD-18-481	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 Asfalti İstanbul Tuzla Org. San. Bölg.
9. Cad. No: 15 Tepeören / Tuzla / İSTANBUL/ TÜRKİYE
Tuzla V.D. 620 [illegible] No:365270
Mersis No: [illegible] 00019