CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-682

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:

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fatih Mah. 1142 Sokak Sarnıç No:35 Gaziemir - İzmir - Turkey

Products: IV Flow Controller, Extension Line, Karman Cannula and Karman Cannula Injector, Arthroscopy Set, Spirometer Filtered Mouthpiece, Skin Marking Set, Mucous Collection Container, Valve Urine Bag, Valve Emesis Bag, Surgical Covers and Drapes, Endoscopy Mouthpiece, Smear Brushes, Amniotic Pouch Perforator, Umbilical Cord Clamp, Sterile Luer Connector Cap (Stopper)

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.5746.01
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 for Class Im devices and with securing and maintaining sterile conditions in accordance with MDD Annex V for Class Is devices covered by this certificate and found that the quality system meets the applicable requirements in MDD Annex V.

Muhteşem Gökhan Yücel
Head of Notified Body

13 July 2020 , Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:
Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V
Certificate Number: 1984-MDD-20-682

Concerned medical devices;

Product Name	Types
IV Flow Controller	IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
	Cylindrical IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
Extension Line	Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
	Pressure Resistant Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
Karman Cannula and Karman Cannula Injector	Karman Cannula (No: 3, 4, 5, 6, 7, 8, 9, 10,12)
	Single Valve Manual Vacuum Aspirator Set, Double Valve Manual Vacuum Aspirator Set, Single Valve Manual Vacuum Aspirator, Double Valve Manual Vacuum Aspirator
	Non-Sterile Single Valve Manual Vacuum Aspirator, Non-Sterile Double Valve Manual Vacuum Aspirator
Arthroscopy Set	Y-Tur Set, Y-Tur Set With Pump
Spirometer Filtered Mouthpiece	Small (26mm, 30mm, 33mm)
	Small With Latch (26mm, 30mm, 33mm)
	Big (30mm, 33mm)
	Big With Latch (30mm, 33mm)
Skin Marking Set	Skin Marking Set, Thin Tipped Skin Marking Set
Mucous Collection Container	Mucous Collection Container (15ml, 25ml, 40ml, 100ml)
	Mucous Collection Container With Hose (40ml)
Valve Urine Bag	White, With Discharge
Valve Emesis Bag	Transparent, White
Surgical Covers and Drapes	Microscope Drape, Camera Cover, Cardboard Camera Cover, Telescopic Camera Cover, Circled Camera Cover, Accordion Folded Camera Cover, Probe Cover, Endoscopy Bag, Scopy Cover, C Arm Scopy Cover, Fluoroscopy Cover, Operating Ceiling Lamp Handgrip Cover
Endoscopy Mouthpiece	-
Smear Brushes	Brush, Spatula
Amniotic Pouch Perforator	-
Umbilical Cord Clamp	-
Sterile Luer Connector Cap (Stopper)	-

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

13 July 2020 , Istanbul, Turkey

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MEDICAL DEVICES DIVISION

Granarolo dell'Emilia (BO), 2024/03/25
CL1/V4

Esteemed

MEDBAR TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.

1142 SOK. NO:35 SARNIÇ GAZİEMİR İZMİR

Notified Body Confirmation Letter Reference: CERBO0215022

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:

MEDBAR TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.

1142 SOK. NO:35 SARNIÇ GAZİEMİR İZMİR TURKEY

SRN Number (if available): TR-MF-000017895

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
Arthroscopy Set	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Mucous Aspirator	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
IV Flow Controller Type: Cylindrical IV Flow Controller	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
IV Flow Controller Type:IV Flow Controller	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Karman Cannula and Karman Cannula Injector (8698881917122MA)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Karman Cannula and Karman Cannula Injector (8698881917139MT)	Class IIa	Identification of the corresponding device under MDD	Certificate No: 1984-MDD-20-682 NB# 1984

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
		✓ Same □ Substitute	
Surgical Covers and Drapes Type: Light Handle Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** C-Arm Scopy Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** Endoscopy Bag	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** Camera Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** Microscope Drape	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** Fluoroscopy Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Surgical Covers and Drapes **Type:** Scopy Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984

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
Surgical Covers and Drapes **Type:** Probe Cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Extension Line	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Spirometer Filtered Mouthpiece	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984
Valve Urine Bag	Class I devices with a measuring function	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 1984-MDD-20-682 NB# 1984

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/25	Rev.00	Initial issue
2024/04/02	Rev.01	The types have been added to some products: **IV Flow Controller** Type: Cylindrical IV Flow Controller **IV Flow Controller** Type:IV Flow Controller **Surgical Covers and Drapes** Type: Light Handle Cover **Surgical Covers and Drapes** Type:C-Arm Scopy Cover **Surgical Covers and Drapes** Type:Endoscopy Bag **Surgical Covers and Drapes**

Date	NB internal reference traceable to each version of the letter	Action
		Type:Camera Cover **Surgical Covers and Drapes** Type:Microscope Drape **Surgical Covers and Drapes** Type:Fluoroscopy Cover **Surgical Covers and Drapes** Type:Scopy Cover **Surgical Covers and Drapes** Type:Probe Cover

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

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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	Medbar Tıbbi Malzemeler Turizm San. Tic A.Ş.
Manufacturer address and contact details	1142 Sokak No:35 Sarnıç Gaziemir-İzmir Hülya URBAY/QMR
Single Registration Number (SRN) (if available)	TR-MF-000017895

Authorised Representative name (if applicable)	-
Authorised Representative address and contact details	-
Single Registration Number (SRN) (if available)	-

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

[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.

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Medbar Tıbbi Malzemeler Turizm San. ve Tic. A.Ş.

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Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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.

  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:

[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

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Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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.

Signed for and on behalf of the manufacturer: Hülya URBAY / QMR

Full Company Name Medbar Tıbbi Malzemeler

Location & Date 22.11.2023 / İzmir

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Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Signature, Print Name, Title	Hülya URBAY/QMR
Contact Details (at least email)	h.urbay@medbar.com.tr

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Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

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/contrac t signed (if applicable)**	**End date of extended validity / transition period**	**Substitute Device(s) (if applicable)**
Y-Type Phototheraphy Eye Band	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Surgical Cover And Drape	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Arthroscopy Set	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Arterial Cannula	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Endoscopy Moutpieces	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Karman Cannula And Manual Vacuum Aspirator	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Pouch Perforator	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Smear Brushes	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Spirometer Filtered Mouthpieces	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Skin Marking Set	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Umbilical Cord Clamp	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-
Valve Urine Bag	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Mucus Collection Container	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Extension Line	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
IV Flow Controller	NB1984 (KİWA)	27 May 2024	Scheduled for March 2024	-	26 September 2024	-
Sterile Luer Connector Cap(Stopper)	NB1984 (KİWA)	27 May 2024	-	-	26 September 2024	-

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