EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2021.106.14528-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: İstem Medikal Tıbbi Cihaz ve San. Tic. Ltd. Şti.
Company Address	: Anadolu Organize Sanayi Bölgesi Mah. 29 Ekim Cad. No:41 Malıköy Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Sodium Hyaluronate Gel - Sınıf III
GMDN	: 44757
Certificate Number	: M.2021.106.14528
Report Number	: MD.3200.IB
Initial Assessment Date	: 12.03.2021
Registration Date	: 07.05.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2021.106.14528 the validity of the certificate M.2021.106.14528-1 will also end.

Company Name : İstem Medikal Tıbbi Cihaz ve San. Tic. Ltd. Şti.

Company Address : Anadolu Organize Sanayi Bölgesi Mah. 29 Ekim Cad. No:41 Malıköy Sincan ANKARA / TURKEY

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

Product : Sterile Sodium Hyaluronate Gel - Sınıf III

GMDN : 44757

Certificate Number : M.2021.106.14528-1
Report Number : MD.3200.IB
Initial Assessment Date : 12.03.2021
Registration Date : 07.05.2021
Revision Date /No : -
Expiry Date : 27.05.2024

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

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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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	İstem Medikal Tıbbi Cihaz ve Sanayi Ticaret Ltd. Şti.
Manufacturer address and contact details	Malıköy, Anadolu OSB Mah, 29 Ekim Cd. No:41, 06909 Sincan/Ankara/TURKEY
Single Registration Number (SRN) (if available)	TR-MF-000017811

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

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

[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.

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

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

[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

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.

Signed for and on behalf of the manufacturer:

İstem Medikal Tıbbi Cihaz ve Sanayi Ticaret Ltd. Şti.

Ankara, 08.05.2024

Levent HAYYAOĞLU

General Manager

İSTEM MEDİKAL
TIBBİ CİHAZ VE SAN.TİC.LTD.ŞTİ.
Anadolu O.S.B. Mah. 29 Ekim Cad.
No: 41 Malıköy / Sincan / ANKARA
Tel: (032) 394 55 62 Fax: 394 55 64
Sincan V.D. 481 008 4741

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/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile Sodium Hyaluronate Gel	M.2021.106.14528, M.2021.106.14528-1	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Lubricant Gel with Lidocaine	M.2021.106.14615 M.2021.106.14615-1	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Lubricant Gel with Lidocaine (CHG Free)	M.2021.106.14616 M.2021.106.14616-1	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile 0,9% Sodium Chloride Solution	M.2021.106.14605 M.2021.106.14605-1	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Sodium Hyaluronate Solution	M.2014.106.3601	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Filter Tur Collector Set (Waterproof, Collector Cover, Drainage Hose,	M.2017.106.8494	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A

[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)

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)
Connecting Clamp, Particule Collection Reserve, Filter)						
Sterile Amorphous Hydrogel	2195-MED-2114102	26.05.2024	SZUTEST Uygunluk Değerlendirme A.Ş., 2195	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Hydrophilic Urinary Catheter (With or without water socket, kit and ready to use)	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Nelaton Urinary Catheter	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Hydrophilic Instillation Urinary/ Catheter (with or without water sachet and Kit)	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Inhalation Water	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A
Sterile Water Soluble Lubricating Gel	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A

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)
Sterile Antibacterial Hydrophilic Urinary Catheter (with or without water sachet, kit and ready to use)	M.2016. 106.6895	27.05.2024	UDEM Belgelendirme A.Ş., 2292	UDEM Belgelendirme A.Ş., 2292	N/A	N/A

Anadolu O.S.B. Mah. 29 Ekim Cad. No.41 Malıköy, SINCAN/ Ankara
Tel: (312) 394 5562 Fax: (312) 394 5564 e-posta: istem@istemmedikal.com

29/04/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER

CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0023/P1

Subject: 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.

To whom it may concern,

This letteris the official document of UDEM A.Ş., a Notified Body (NB) designated in accordance with Regulation (EU) 2017/745 (MDR) and identified in NANDO with the number 2292, in accordance with the first subparagraph of Chapter 4.3 of Annex VII of the MDR and confirms that UDEM A.Ş. has received an application and has signed a written contract in accordance with the second subparagraph of Chapter 4.3 of Annex VII to the MDR with the following manufacturer:

Company Name:	İSTEM MEDİKAL TIBBİ CİHAZ VE SAN. TİC. LTD. ŞTİ.
Company Address:	ANADOLU OSB MAH. 29 EKİM CAD. NO:41 MALIKÖY, SİNCAN, ANKARA, TÜRKİYE
SRN Number (if any):	TR-MF-000017811

The devices covered by the above-mentioned official application and written contract are defined in the tables below. Table 1 describes the devices for which an MDR application has been received, a written contract has been made and UDEM A.Ş. is also responsible for the appropriate surveillance of the relevant devices within the scope of the 93/42/EEC Medical Device Directive (MDD). Table 2 identifies devices for which an MDR application has been received and a written contract has been concluded, but for which UDEM A.Ş. has not yet taken appropriate surveillance responsibility for the relevant devices under the MDD.

For devices covered by certificates issued under the MDD which expire after 26 May 2021 and before 20 March 2023 without withdrawal, this letter also confirms that the manufacturer has provided evidence that the competent authority of the Member State under the MDR up to the date of expiry of the MDD certificate has granted an exception or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of the MDR or Article 97(1) of the MDR for the devices concerned until 20 March 2023.

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 class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in a sterile condition or with a measurement function,
- 31 December 2028 for devices for which the conformity assessment procedure in accordance with Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure in accordance with the MDR requires the involvement of a notified body.

UDEM A.Ş. General Manager Name-Surname:	MUSTAFA MEMİŞOĞLU
Date:	29.04.2024
Stamp-Signature:	UDEM ULUSLARARASI BELGELENDİRME UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya / ANKARA Tel: (0.312) 443 03 7[illegible] (0.312) 443 03 7[illegible] DOĞANBEY VERGİ Dairesi : 885 044 258

Table-1 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
STERILE HYDROPHILIC URINARY CATHETER	Class I devices placed on the market in sterile condition	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
STERILE NELATON CATHETER	Class I devices placed on the market in sterile condition	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
STERILE ANTIBACTERIAL HYDROPHILIC URINARY CATHETER	Class I devices placed on the market in sterile condition	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
STERILE HYDROPHILIC INSTILLATION CATHETER	Class I devices placed on the market in sterile condition	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
WATER SOLUBLE LUBRICATING GEL	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
STERILE INHALATION WATER	Class IIa	N/A	Certificate 1: M.2016.106.6895 Certificate 1: 2292
STERILE LUBRICANT GEL WITH LIDOCAINE	Class III	N/A	Certificate 1: M.2021.106.14615 Certificate 1: 2292 Certificate 2: M.2021.106.14615-1 Certificate 2: 2292
STERILE LUBRICANT GEL WITH LIDOCAINE (CHG FREE)	Class III	N/A	Certificate 1: M.2021.106.14616 Certificate 1: 2292 Certificate 2: M.2021.106.14616-1 Certificate 2: 2292
STERILE 0.9% SODIUM CHLORIDE SOLUTION	Class III	N/A	Certificate 1: M.2021.106.14605 Certificate 1: 2292 Certificate 2: M.2021.106.14605-1 Certificate 2: 2292
STERILE SODIUM HYALURONATE SOLUTION	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1:M.2014.106.3601 Certificate 1: 2292
STERILE SODIUM HYALURONATE GEL	Class III	N/A	Certificate 1: M.2021.106.14528 Certificate 1: 2292 Certificate 2: M.2021.106.14528-1 Certificate 2: 2292
STERILE, INJECTABLE IMPLANT FOR	Class III	N/A	Certificate 1: M.2021.106.14286 Certificate 1: 2292

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VESICOURETERAL (VUR) THERAPY			Certificate 2: M.2021.106.14286-1 Certificate 2: 2292
FILTER TUR COLLECTOR SET	Class I devices placed on the market in sterile condition	N/A	Certificate 1: M.2017.106.8494 Certificate 1: 2292
STERILE AMORPHOUS HYDROGEL	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: 2195-MED-2114102 Certificate 1: 2195 Certificate 2: 2195-MED-2114102-D01 Certificate 2: 2195

Tablo-2 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Not Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

CONTRACT CONFIRMATION LETTER REVISION HISTORY

Date	Contract Confirmation Letter Revision Number	Revision Explanation
29/04/2024	CL.CONTRACT.UDEM.0023/P1	Preparation of contract confirmation letter

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Türkiye Medicine and Medical Devices Agency

TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI

24.05.2024

Number: E-61749811 511.99-1488579
Subject: 2023-KK-1

İSTEM MEDİKAL TIBBİ CİHAZ VE SANAYİ TİCARET LİMİTED ŞİRKETİ
Maliköy Anadolu O.S.B. Mh. 29 Ekim Cad. No:41/. Sincan ANKARA

Reference: Your letter dated 02.05.2024, No. E-48535386-511.01.99-3124665, Transaction No. 6038998

Your application related to your request for the extension of the validity period of EC Certificate No. M.2021.106.14528 has been reviewed.

To mitigate the risk of supply disruption of medical devices, the European Commission published in the Official Journal of the EU on March 20, 2023, the Regulation *"(EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices*," effective from March 20, 2023.

In line with the EU's updated medical device legislation harmonization efforts, the *"Regulation Amending the Medical Device Regulation"* and the *"Regulation Amending the Regulation on In Vitro Diagnostic Medical Devices,"* in parallel with *Regulation (EU) 2023/607 of the European Parliament and of the Council*, were published in the Official Gazette on April 2, 2023, and the relevant changes were made to the *Medical Device Regulation and the Regulation on In Vitro Diagnostic Medical Devices.*

In this context, our announcement titled *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607 (No. 2023/KK-1)"* explaining the procedures and principles for the implementation of these transitional provisions was published on our Agency's website and the ÜTS Portal on April 3, 2023, and came into force.

In this regard, the application has been evaluated within the scope of the *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607 (No. 2023/KK-1),"* and it has been deemed appropriate to extend the validity period of *EC Certificate No. M.2021.106.14528* until **December 31, 2027.** Accordingly, it is requested to submit a document registration/update application in the ÜTS system within the scope of our announcement titled *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607* ***(No. 2023/KK-2)****,"* attaching this response letter and its annexes to the relevant application.

We kindly request your information and necessary action.

Dr. Mehmet Hakan FIRAT
Vice President of the Institution

Attachments
1-Annex-1 (2 pages)
2-Annex -2 (4 pages)

Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA
Telephone Number: (0 312) 218 30 00 Fax Number: (0 312) 218 34 60
E-mail: halkla.iliskiler@titck.gov.tr Internet Adress: https://www.titck.gov.tr
Kep Adress: titck@hs01.kep.tr

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Türkiye Medicine and Medical Devices Agency

TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI

24.05.2024

Number: E-61749811 511.99-1488576
Subject: 2023-KK-1

İSTEM MEDİKAL TIBBİ CİHAZ VE SANAYİ TİCARET LİMİTED ŞİRKETİ
Maliköy Anadolu O.S.B. Mh. 29 Ekim Cad. No:41/. Sincan ANKARA

Reference: Your letter dated 02.05.2024, No. E-48535386-511.01.99-3124667, Transaction No. 6039019

Your application related to your request for the extension of the validity period of EC Certificate No. M.2021.106.14528-1 has been reviewed.

To mitigate the risk of supply disruption of medical devices, the European Commission published in the Official Journal of the EU on March 20, 2023, the Regulation *"(EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices*," effective from March 20, 2023.

In line with the EU's updated medical device legislation harmonization efforts, the *"Regulation Amending the Medical Device Regulation"* and the *"Regulation Amending the Regulation on In Vitro Diagnostic Medical Devices,"* in parallel with *Regulation (EU) 2023/607 of the European Parliament and of the Council*, were published in the Official Gazette on April 2, 2023, and the relevant changes were made to the *Medical Device Regulation and the Regulation on In Vitro Diagnostic Medical Devices.*

In this context, our announcement titled *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607 (No. 2023/KK-1)"* explaining the procedures and principles for the implementation of these transitional provisions was published on our Agency's website and the ÜTS Portal on April 3, 2023, and came into force.

In this regard, the application has been evaluated within the scope of the *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607 (No. 2023/KK-1),"* and it has been deemed appropriate to extend the validity period of *EC Certificate No. M.2021.106.14528* until **December 31, 2027.** Accordingly, it is requested to submit a document registration/update application in the ÜTS system within the scope of our announcement titled *"Announcement on the Implementation of the Provisions of Regulation (EU) 2023/607* ***(No. 2023/KK-2)****,"* attaching this response letter and its annexes to the relevant application.

We kindly request your information and necessary action.

Dr. Mehmet Hakan FIRAT
Vice President of the Institution

Attachments
1-Annex-1 (2 pages)
2-Annex -2 (4 pages)

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