S E R T I F I K A T A S

Visiška kokybės užtikrinimo sistema

Medicinos prietaisų direktyvos 93/42/ESC II priedas (išskyrus 4 skirsnį)

Įmonės pavadinimas

Kompanijos adresas

Gamybos svetainė

Susijusios direktyvos ir priedas produktas

Sertifikato numerio ataskaitos numeris

Pirminio vertinimo data Registracijos data

: Technocast Otomotiv San ve Tic. A.Ş.

: Organizuoti Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Kad. No:12 Çerkezköy TEKIRDAG / TURKIJA

: Technocast Otomotiv Sanayi ir Ticaret A.Ş Medikal Şubesi

Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Kad. No:26 Çerkezköy TEKiRDAG / TURKIJA

: Medicinos prietaisų direktyva 93/42/EEB – II priedas (išskyrus 4 skirsnį)

- Ištraukimo krepšelis - Ila klasė - Sterilus
- Griebimo žnyplės - Ila klasė - Sterilus
- Sfinkterotomas - Ilb klasė - Sterilus
- Polipektomijos kilpai - Ilb klasė - Sterilus
- E.R.C.P kateteris - klasė yra - sterilus
- Akmens ištraukimo balionas - Ila klasė - Sterilus
- Tulžies stentas - Ila klasė - Sterilus

: 37141, 37141, 58039, 38827, 16429, 46715, 10696

: M.2016.106.7002

: MD.3157.YB

: 2016-07-27

: 2016-10-04

Pakartotinio sertifikavimo vertinimo data: 2020-03-04

UDEM lnterri ona îfication

Pakartotinio išleidimo data / Nėra peržiūros datos / Nr

: 2020-06-10/01

Audito mokymas ntre Pramonė

ir Trade Inc. Co.

Galiojimo laikas: 2024-05-27

07/05/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER

CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0180/P1/R1

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:	TECHNOCAST OTOMOTİV SAN VE TİC. A.Ş.
Company Address:	**CENTER:** ÇERKEZKÖY ORGANİZE SANAYİ BÖLGESİ GAZİ OSMAN PAŞA MAH.6. CADDE NO:12 ÇERKEZKÖY/TEKİRDAĞ **MANUFACTURING ADDRESS:** TECHNOCAST OTOMOTİV SANAYİ VE TİCARET A.Ş MEDİKAL ŞUBESİ, ÇERKEZKÖY ORGANİZE SANAYİ BÖLGESİ GAZİ OSMAN PAŞA MAH.6.CADDE NO:26 ÇERKEZKÖY/TEKİRDAĞ
SRN Number (if any):	TR-MF-000030603

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:

III klasės priemonių CE pratęsta iki 2026 06 26

- 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)

IIb klasės priemonių (skirtų odontologijai) CE pratęsta iki 2027 12 31

- 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,

IIb, IIa klasės priemonių CE pratęsta iki 2027 12 31

- 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:	
Date:	07.05.2024
Stamp-Signature:	UDEM ULUSLARARASI BELGELENDİRME

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
BILIARY STENT SET	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2021.106.14330 Certificate 1: 2292
BILIARY STENT	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
SPHINCTEROTOME	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
EXTRACTION BASKET	Class IIa	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
STONE EXTRACTION BALLOON	Class IIa	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292

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
06/05/2024	CL.CONTRACT.UDEM.0180/P1	Preparation of contract confirmation letter
07/05/2024	CL.CONTRACT.UDEM.0180/P1/R1	Adding the manufacturing location address

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Ümitköy Çankaya/Ankara
0(312) 443 03 90
mdr@udem.com.tr

CERTIFICATE

Full Quality Assurance System

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

Company Name	: Technocast Otomotiv San ve Tic. A.Ş.
Company Address	: Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12 Çerkezköy TEKİRDAĞ / TURKEY
Manufacturing Site	: Technocast Otomotiv Sanayi ve Ticaret A.Ş Medikal Şubesi Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad. No:26 Çerkezköy TEKİRDAĞ / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Extraction Basket - Class IIa - Sterile - Grasping Forceps - Class IIa - Sterile - Sphincterotome - Class IIb - Sterile - Polypectomy Snare - Class IIb - Sterile - E.R.C.P Catheter - Class Is - Sterile - Stone Extraction Balloon - Class IIa - Sterile - Biliary Stent - Class IIa - Sterile
GMDN	: 37141, 37141, 58039, 38827, 16429, 46715, 10696
Certificate Number	: M.2016.106.7002
Report Number	: MD.3157.YB
Initial Assessment Date	: 27.07.2016
Registration Date	: 04.10.2016
Recertification Assessment Date	: 04.03.2020
Reissue Date / No	: 10.06.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

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 applied 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 certificate 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 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 validity 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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