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