

26.09.2024

**NOTIFIED BODY CONTRACT CONFIRMATION LETTER****CONTRACT CONFIRMATION LETTER NO: CNT\_ UDEM.0419/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 letter is 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:

<b>Company Name:</b>	EgiFix Medical
<b>Company Address:</b>	Plot 107,108,118 zone 2 industrial Area, Quweisna, Menoufia, Egypt
<b>SRN Number (if any):</b>	EG-MF-000026764

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:	26.09.2024
Stamp-Signature:	 <p>UDEM ULUSLARARASI BELGELENDİRME DEN. EĞİT. MERKEZİ SAN. VE TİC. A.Ş. Mutlukent Mah. No:10 Ümitköy Çankaya/Ankara Tel:(0312) 443 03 90 Vergi Dairesi 885 044 2587</p>

**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
<b>Sterile Total and Modular Hip Replacement: Cemented Total Hip Replacement</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total and Modular Hip Replacement: Cementless Total Hip Replacement</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total and Modular Hip Replacement: Bipolar Hip Replacement</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total and Modular Hip Replacement: Modular Total Hip Replacement</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total and Modular Hip Replacement: Revision Total Hip Replacement (Cup &amp; Stem)</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total Knee Replacement: PS Total Knee</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total Knee Replacement: CR Total Knee</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total Knee Replacement: Mobile Total Knee</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Sterile Total Knee Replacement: Modular Total Knee</b>	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Non-Sterile Spinal Cage System: Anterior Cervical Cage</b>	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
<b>Non-Sterile Spinal Cage System: Expandable Cervical Corpectomy Cage system</b>	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653

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
Non-Sterile Spinal Cage System: Cervical Corpectomy Cage	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Spinal Cage System: Anterior Lumbar Cage	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Spinal Cage System: Posterior Lumbar Interbody Cage	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Spinal Cage System: Transforaminal Lumbar Interbody cage	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Spinal Cage System: Expandable Lumbar Corpectomy Cage system	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Spinal Cage System: Lumbar Corpectomy Cage	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nais System: Interlocking Intramedullary Nail femur Antigrade (excluding Locking Screws)	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nais System: Interlocking Intramedullary Nail femur Retrograde (excluding Locking Screws)	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nais System: Interlocking Intramedullary Nail femur Trochanteric (excluding Locking Screws)	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nais System: Proximal Femoral Interlocking Nail (excluding Locking Screws)	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nais System: Interlocking intramedullary	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653

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
nail Humerus (excluding Locking Screws)			
Non-Sterile Intramedullary Nails System: Interlocking intramedullary nail tibia (excluding Locking Screws)	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Intramedullary Nails System: Intramedullary Flexible Nail	Class IIb	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Non-Sterile Spinal Screw System: Top Loading Thoracolumbar Pedicular Screws (hooks)	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653
Device 26. Non-Sterile Spinal Screw System: Top loading Posterior Cervical Screws (hooks)	Class III	N/A	Sertifika 1: 301041536 Sertifika 1: 0653

**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
26.09.2024	CNT_ UDEM.0419/P1/R0	Preparation of contract confirmation letter