

29/04/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER**CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0001/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:

Company Name:	MATEK MEDİKAL AYGITLAR TEKNOLOJİ SANAYİ TİCARET A.Ş.
Company Address:	İVEDİK OSB. MAH. 2273 CAD. NO:10 YENİMAHALLE / ANKARA / TÜRKİYE
SRN Number (if any):	TR-MF-000017768

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:	 <p>UDEM ULUSLARARASI BELGELENDİRME UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş. Mutlukent Mah. 2073. Sok. No:10 Ümitköy - Çankaya / ANKARA/ Tel: (0312) 443 03 90 (Fax) Fax: (0312) 443 03 7 T.C. GANBEK Yerel Dairesi : 0312 044 20</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
Bone Marrow Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Bone Marrow Biopsy Needle-Captura System	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Bone Marrow Aspiration Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Bone Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Chiba Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set- Chiba	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Amniocentesis Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Chorionic Villus Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Cordecentesis Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Westcott Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set - Westcott	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Franseen Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set - Franseen	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Liver Biopsy Set	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Automatic Biopsy Gun Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Automatic Biopsy Gun Needle-M Type	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
OptiCut Semi-Automatic Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Vacumat Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OptiCore Automatic Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Automatic Biopsy Gun Needle-P Type	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Automatic Biopsy Gun Needle-N Type	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set – Semi Automatic	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set –Biopsy Gun Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Set – Automatic Biopsy Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Breast Localization Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Breast Localization Needle Double Hooked	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Breast Localization Needle Double Wire	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Percutaneous Access Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Trocar Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Sheated Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Coaxial Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Vitacath Transbronchial Aspiration Needle	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Injection Needle, Metal	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Injection Needle, Metal, Plastic Hub	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Injection Needle, Plastic	Class IIa	N/A	Certificate 1: 1984-MDD-21-821 Certificate 1: 1984
Intraosseous Infusion Needle with Driver	Class IIa	N/A	Certificate 1: M.2020.106.13295 Certificate 1: 2292
Manual Intraosseous Infusion Needle	Class IIa	N/A	Certificate 1: M.2020.106.13295 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
29/04/2024	CL.CONTRACT.UDEM.0001/P1	Preparation of contract confirmation letter