



UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2024/12/26

**YILKAL MEDİKAL SAĞLIK ÜRÜNLERİ PAZARLAMA
DAĞITIM SAN. VE TIC. LTD. ŞTI
Fevzi Çakmak Mah. 10670 Sokak
No:26/B-1 Karatay
KONYA/TÜRKİYE**

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1867-23-01.NBCL.0035/R01

To whom it may concern,

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.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2023/09/13) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2023/09/13) with the following manufacturer:

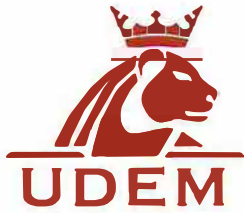
**YILKAL MEDİKAL SAĞLIK ÜRÜNLERİ PAZARLAMA (ALLIANCE DZ)
DAĞITIM SAN. VE TIC. LTD. ŞTI
Fevzi Çakmak Mah. 10670 Sokak
No:26/B-1 Karatay
KONYA/TÜRKİYE
SRN Number (if available): TR-MF-000031561**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb
Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434
E-mail: info@udemadriatic.com

UDEM OIB: 50375070784
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb
Tel: (1) 4819 601 Fax: (1) 4819 434
www.udemadriatic.com

UDFRM.235/01-08.05.2023/07.04.2023 Page 1 / 4



In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

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 other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager


UDEM Adriatic d.o.o.
OIB: 50373079784
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb
Tel: (1) 4819601 Fax: (1) 4819434
www.udemadriatic.com


UDEM Adriatic d.o.o.
OIB: 50373079784
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb
Tel: (1) 4819601 Fax: (1) 4819434
www.udemadriatic.com

UDEM Adriatic d.o.o.

Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434

E-mail: info@udemadriatic.com

UDFRM.235/01-08.05.2023/07.04.2023 Page 2 / 4



Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (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
1.Nebulizer Set	Class IIa	N/A	Certificate 1: Full Quality Assurance System Certificate No: M.2019.106.11199 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB 2292)
2.Oxygen Mask (with or without Reservoir)	Class IIa	N/A	Certificate 1: Full Quality Assurance System Certificate No: M.2019.106.11199 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB 2292)
3.Nasal Oxygen Cannula	Class IIa	N/A	Certificate 1: Full Quality Assurance System Certificate No: M.2019.106.11199 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB 2292)

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (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

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Phone: +385 (1) 4819 601 • Fax: +385 (1) 4819 434

E-mail: info@udemadriatic.com

 **UDEM Adriatic d.o.o.**
UDEM OIB:50373679784
Radnička cesta 54/R3, Green Gold Centar, IV.kat,Zagreb
Tel: +385 1 4819601 Fax: (1)4819434
www.udemadriatic.com

UDFRM.235/01-08.05.2023/07.04.2023 Page 3 / 4



Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/11/07	2023.MDR.1867-23-01.NBCL.0035	Initial issue
2024/12/26	2023.MDR.1867-23-01.NBCL.0035/R01	On the date of 2024/09/26, MDD surveillance of related legacy devices was transferred to UDEM Adriatic d.o.o from MDD Notified Body. For this reason related products have been moved from Table 2 to Table 1.

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Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434

E-mail: info@udemadriatic.com


UDEM Adriatic d.o.o.
UDEM OIB: 50373079764
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb
Tel: (148) 9601 Fax: (148) 19434
www.udemadriatic.com

UDFRM.235/01-08.05.2023/07.04.2023 Page 4 / 4