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

2024/04/22

CDM Center of Excellence Ltd.
Golden Land Building Office 1302A
Liangmaqiao Road No.32
Chaoyang District, 100125
Beijing China

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2024.MDR.1642.NBCL.0117

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 2023/10/30) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2023/10/30) with the following manufacturer:

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Golden Land Building Office 1302A
Liangmaqiao Road No.32
Chaoyang District, 100125
Beijing China
SRN Number (if available): CN-MF-000013454

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.

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covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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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
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is <u>NOT</u> 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
Disposable Syringe Sets	Class IIa	N/A	**<u>Certificate 1:</u>** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Sterile Irrigation Needles For Single Use	Class I devices placed on the market in sterile condition	N/A	**<u>Certificate 1:</u>** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Disposable Needles	Class IIa	N/A	**<u>Certificate 1:</u>** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)

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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
Dental Needle	Class IIa	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Dental Root-Canal Instruments	Class IIa	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Disposable Saliva Ejectors	Class IIa	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Disposable Aspirator Tips	Class IIa	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Disposable Dental Air Water Syringe Tips	Class IIa	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)
Sterile Non-woven Surgical Gowns	Class I devices placed on the market in sterile condition	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)

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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 Gauze Swabs without x-ray detectable	Class I devices placed on the market in sterile condition	N/A	**Certificate 1:** Production Quality Assurance Certificate No: DD 60146829 0001 TÜV Rheinland LGA Products GmbH (0197)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/22	2024.MDR.1642.NBCL.0117	Initial issue

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