EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A
(Class Is, Im and Ir Devices)

Certificate Number: M.2023.MDR.1017

Manufacturer Name	: İdol Hastane Ürünleri San. ve Tic. A.Ş.
Manufacturer Address	: Altınova Sinan Mah. 39/1 Sokak no :75 Kepez, Antalya, Turkiye
Single registration number-SRN	: TR-MF-000026386
Authorised Representative Name ***(If applicable)***	: NA
Authorised Representative Address	: NA
Product Scope	: See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality assurance system in accordance with (EU) 2017/745 Medical Devices Regulation Annex XI Part A, UDEM Adriatic d.o.o hereby declares that the requirements of Annex XI Part A of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.
The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according Annex XI Part A Section 7 of the aforementioned Regulation.
For the devices covered by this certificate, the involvement of UDEM Adriatic d.o.o. in the conformity assessment procedures is limited: in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions; in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

Report Number	: MDR.1464
Date of Issue	: 15/05/2023
Recertification Date	: -
Reissue Date/No	: 24/05/2023/01
Date of Expiry	: 14/05/2028

If any, Previous Certificate(s) No: none

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. UDEM 2696

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

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