



EC DECLARATION OF CONFORMITY

Manufacturer Name: Medikal Olusum Sanayi ve Ticaret Limited Sirketi

Manufacturer Address: Dayyaka Mah. 2038. Cad. No: 4/20 Ic Kapi No:2, 06980,
Kahramankazan/Ankara/Turkey

SRN (Single Registration Number): TR-MF-000026274

Classification: Class A

Conformity assessment route: Medikal Olusum Sanayi ve Ticaret Limited Sirketi uses the following procedures for the CE-labeling of their products according to the Regulation IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices):

Basic UDI-DI	UDI-DI	Product Code	Product Name
869893434BPIB00005H6	08698934340143	BPIB00005	Urine Container 100mL

This declaration of conformity is issued under the sole responsibility of Medikal Olusum Sanayi ve Ticaret Limited Sirketi. We hereby declare that the medical device(s) specified above meet the provision of Regulation IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices) in vitro medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by IQR International. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Osman Bařhan

Chair of the Board

18.12.2023

