



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):

Product Code	Product Description	UDI-DI	Basic UDI-DI
BPIB00010	Urine Container 60mL	08683052629836	8683052629BPIB000106E
BPIB00005	Urine Container 100mL	08698934340143	869893434BPIB00005H6
BPIB00016	Urine Container 120mL	08684341089119	8684341089BPIB0001694
BPIB00020	Urine Container 200mL	08683052629850	8683052629BPIB000206H
BPVI00003	Urine Container with Integrated Transfer Device 60mL	08683052629874	8683052629BPVI00003G9
BPVI00001	Urine Container with Integrated Transfer Device 100mL	08683052629584	8683052629BPVI00001G5
BPIB00013	24h Urine Collection Container 5000mL White		
BPIB00015	24h Urine Collection Container 5000mL Amber		
BPIB00008	24h Urine Collection Container 3000mL Vacuumed Cap, White	08684341089010	8684341089BPIB0000895
BPIB00012	24h Urine Collection Container 3000mL Vacuumed Cap, Amber		

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 BAŞHAN
Chair of the Board
25.02.2025

