



## 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
BPIB00007	Urine Container 50mL	08683052629812	8683052629BPIB000076R
BPIB00006	Urine Container 50mL, individually packaged	08683052629829	8683052629BPIB000066P
BPIB00010	Urine Container 60mL	08683052629836	8683052629BPIB000106E
BPIB00011	Urine Container 60mL, individually packaged	08683052629843	8683052629BPIB000116G
BPIB00005	Urine Container 100mL	08698934340143	869893434BPIB00005H6
BPIB00003	Urine Container 100mL, individually packaged	08683052629607	8683052629BPIB000036H
BPIB00016	Urine Container 120mL	08684341089119	8684341089BPIB0001694
BPIB00017	Urine Container 120mL, individually packaged	08684341089126	8684341089BPIB0001796
BPIB00020	Urine Container 200mL	08683052629850	8683052629BPIB000206H
BPIB00021	Urine Container 200mL, individually packaged	08683052629867	8683052629BPIB000216K
BPVI00003	Urine Container with Integrated Transfer Device 60mL	08683052629874	8683052629BPVI00003G9
BPVI00004	Urine Container with Integrated Transfer Device 60mL, individually packaged	08683052629881	8683052629BPVI00004GB
BPVI00001	Urine Container with Integrated Transfer Device 100mL	08683052629584	8683052629BPVI00001G5
BPVI00007	Urine Container with Integrated Transfer Device 100mL, individually packaged	08683052629898	8683052629BPVI00007GH
BPPO00001	Urinal Bottle 750mL	08683052629751	8683052629BPPO00001FD
BPIB00001	24h Urine Collection Container 3000mL White	08698934340020	869893434BPIB00001GW
BPIB00002	24h Urine Collection Container 3000mL Amber	08684341089027	8684341089BPIB000028R
BPIB00008	24h Urine Collection Container 3000mL Vacuumed Cap, White	08684341089010	8684341089BPIB0000895

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

