



## 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
BPIB00020	Urine Container 200mL	08683052629850	8683052629BPIB000206H
BPTA00006	Sharps Container 2L	08683052629119	8683052629BPTA00006C5

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  
10.01.2025

