



## EC DECLARATION OF CONFORMITY

**Manufacturer Name:** Medikal Olusum Sanayi ve Ticaret Limited Sirketi

**Manufacturer Address:** Dayyaka Mah. 2038. Cad. No: 4/20 Kapı No:2, 06980,

**SRN (Single Registration Number):** Kahramankazan/Ankara/Turkey 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
BPKK00015	Embedding Cassette with Lid	08698934340174	869893434BPKK00015MY
BPPP00001	Pasteur Pipette 1 ml	08684341089348	8684341089BPPP00001J4
BPPP00003	Pasteur Pipette 1 ml Sterile	08684341089355	8684341089BPPP00003J8
BPPP00002	Pasteur Pipette 3 ml	08684341089362	8684341089BPPP00002J6
BPPP00004	Pasteur Pipette 3 ml Sterile	08684341089379	8684341089BPPP00004JA
BPMT00001	Plastic Mape-20 Lam	08684341089386	8684341089BPMT00001J5

This declaration of conformity is issued under the sole responsibility of Medikal Olusum San. ve Tic. Ltd. Sti. 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  
30.07.2025

