



EC DECLARATION OF CONFORMITY

Manufacturer Name: Medikal Olusum Sanayi ve Ticaret Limited Sirketi
Manufacturer Address: Dagyaka 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
BPGK00003	Faeces Container 15mL	08684341089102	8684341089BPGK00003BE
BPGK00005	Faeces Container 15mL, individually packaged	08684341089096	8684341089BPGK00005BJ
BPGK00001	Faeces Container 25-30mL	08698934340105	869893434BPGK00001KH
BPGK00004	Faeces Container 25-30mL, individually packaged	08684341089058	8684341089BPGK00004BG
BPGK00002	Faeces Container 50mL	08698934340129	869893434BPGK00002KK

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
16.07.2025

