



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
BPTA00001	Sharps Container 0.2L	08683052629768	8683052629BPTA00001BT
BPTA00002	Sharps Container 0.5L	08683052629775	8683052629BPTA00002BV
BPTA00003	Sharps Container 0.7L	08683052629782	8683052629BPTA00003BX
BPTA00004	Sharps Container 1L	08683052629799	8683052629BPTA00004BZ
BPTA00005	Sharps Container 1.3L	08683052629065	8683052629BPTA00005C3
BPTA00006	Sharps Container 2L	08683052629119	8683052629BPTA00006C5
BPTA00007	Sharps Container 3L	08683052629126	8683052629BPTA00007C7
BPTA00008	Sharps Container 5L	08683052629072	8683052629BPTA00008C9
BPTA00009	Sharps Container 7.5L	08683052629386	8683052629BPTA00009CB
BPTA00010	Sharps Container 10L	08683052629089	8683052629BPTA00010BU
BPTA00011	Sharps Container 27-30L	08683052629096	8683052629BPTA00011BW
BPTA00012	Sharps Container 30-32L	08683052629805	8683052629BPTA00012BY

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

