



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
BPTA00004	Sharps Container 1L	08683052629799	8683052629BPTA00004BZ
BPTA00007	Sharps Container 3L	08683052629126	8683052629BPTA00007C7
BPTA00008	Sharps Container 5L	08683052629072	8683052629BPTA00008C9

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
15.01.2025

