



DECLARATION OF CONFORMITY according to 2017/745 (EU) MDR

We, manufacturer,

Maya Ambalaj Basım ve Dış Ticaret Limited Şirketi

Organize Sanayi Bölgesi, 27sk no 8, Merkez

70100 Karaman Türkiye

Declare on our sole responsibility that the following listed medical device

Product Name	Kidney Bowl
Basic UDI-DI	8684468204518DE
UDI-DI (GTIN)	08684468204518
Intended Use	The kidney dish is used as a basin for body fluids or for transporting medical/surgical materials or instruments in the non-sterile area
SRN (Single registration number)	TR-MF-000039025

is in conformity with the general safety and performance requirements according to Annex I of EU Regulation 2017/745, including its additions and amendments, as well as the technical documentation and the conformity assessment procedure according to Annex IV.

In accordance with the classification provisions by rule 1 of EU Regulation 2017/745 Annex VIII the product is classified as Class I medical devices.

Regarding to the use and utilization of the listed products, we emphasize that the instruction for use (see labelling on packaging) as well as the appropriate application and safety rules shall be followed in particular. The user of the product bears the sole responsibility caused by improper usage or other than the intended use, In terms of the evidence of conformity all relevant documents are filed in our premises in accordance with current regulations and availability for the authorities at any time.

PRODUCT:	PRODUCT DESCRIPTION:	GMDN/EMDN CODE:	APPLIED STANDARDS :
	Dimensions :255x152x45mm Weight : 22gr (+/- 3g) Material: 100% paper pulp Capacity:700ml Color: Natural brown	GMDN Code: 42871 Emesis Bowl, Single-Use EMDN Code: V0402- Clinical use, Trays and bowls	ISO 9001:2015 ISO 13485:2016 

The Declaration is valid until further changes.

Karaman/ 25.05.2026

Place and date



Maya Ambalaj
Basım ve Dış Tic. Ltd. Şti
Organize Sanayi Bölgesi 27. Cadde No:8
Merkez Karaman Karaman / D 454 054 6131

General Manager
Hakan Tavukçuoğlu

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