


EU DECLARATION OF CONFORMITY

Manufacturer name	Optium Medikal Ltd.Sti.			
Registered address	Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZİANTEP TURKEY			
Telephone	+90 850 807 6284			
Fax	+90 850 807 6284			
E-mail	info@optium.com.tr			
Brand				
Directive	Regulation (EU) 2017/745 on medical devices			
Conformity Assessment	Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III)			
Classification of the product as the medical device:	According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function)			
Basic UDI-DI	868432544044OTH2Z			
Products	MODEL	Product Name	UDI-DI Number	GMDN
	INOXY 161	Bowl Stand Single	8684325441315	42893
	INOXY 162	Bowl Stand Double	8684325441322	42893
	INOXY 163	Kick Bucket	8684325441339	42893
	INOXY 171	Escabo, 1 Step, Stainless Steel	8684325441407	42893
	INOXY 172	Escabo, 2 Step, Stainless Steel	8684325441414	42893
	INOXY 185	Medical Wastage Trolley, 20Liter	8684325441421	
	INOXY 186	Medical Wastage Container, 450 Liters	8684325441438	
	INOXY 312	Waste Bin, Stainless Steel, 12Lt	8684325441537	42893
	INOXY 316	Waste Bin, Stainless Steel, 16Lt	8684325441544	42893
	INOXY 320	Waste Bin, Stainless Steel, 20Lt	8684325441551	42893
Description and function designation:	Stainless steel hospital furniture equipment including all applicable accessories.			

WE HEREWITH DECLARE THAT THOSE ABOVE PRODUCTS WITH CE MARKING WHICH ARE MANUFACTURED BY OUR COMPANY ALL COMPLY WITH REGULATION (EU) 2017/745 ON MEDICAL DEVICES, AND REALIZE THEIR EXPECTED USES. ALL CE FILES HAVE BEEN CERTIFIED BY THE COMPANY, CONSEQUENTLY THEIR AUTHENTICITY HAS BEEN QUARANTEED.

Harmonised Standarts

The said products fulfills the requirements of these harmonized technical standards which were used for assessing of conformity

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

Place, Date of Issue : GAZİANTEP / 12.08.2021
Approved By : Ahmet DAL / General Manager
Stamp and Signature :

