


## EU DECLARATION OF CONFORMITY

<b>Manufacturer name</b>	Optium Medikal Ltd.Sti.
<b>Registered address</b>	Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZIANTEP TURKEY
<b>Telephone</b>	+90 850 807 6284
<b>Fax</b>	+90 850 807 6284
<b>E-mail</b>	<a href="mailto:info@optium.com.tr">info@optium.com.tr</a>
<b>Brand</b>	
<b>Directive</b>	Regulation (EU) 2017/745 on medical devices
<b>Conformity Assessment</b>	Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III)
<b>Classification of the product as the medical device:</b>	According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function)
<b>Basic UDI-DI</b>	868432544044OTH2Z

Products	MODEL	Product Name	UDI-DI Number	GMDN
	INOXY 131	Mayo Trolley, Hydraulic operated	8684325441100	36801
	INOXY 132	Mayo Trolley, Manual	8684325441117	36801
	INOXY 133	Instrument Trolley with drawer	8684325441124	40542
	INOXY 134	Instrument Trolley, 2 Shelves	8684325441131	40542
	INOXY 135	Instrument Trolley, 3 Shelves	8684325441148	40542
	INOXY 136	Work Table	8684325441155	13959
	INOXY 137	Half Moon Trolley	8684325441162	40542
	INOXY 138	Dressing Trolley	8684325441179	40542
	INOXY 139	Dressing Trolley	8684325441186	40542
	INOXY 195	Instrument Trolley with Drawer	8684325441445	40542
	INOXY 196	Dressing Trolley with 2 Drawer	8684325441452	40542
	INOXY 197	Dressing Trolley with 2 Drawer	8684325441469	40542
	INOXY 215	Slipper Trolley	8684325441476	
	INOXY 216	Linen Trolley	8684325441483	
<b>Description and function designation:</b>	Stainless steel trolleys and tables intended for use to keep things and instruments during treatments 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 GUARANTEED.

**Harmonised Standards**

The said products fulfill 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 : GAZIANTEP / 12.08.2021  
 Approved By : Ahmet DAL / General Manager  
 Stamp and Signature :

