


EU DECLARATION OF CONFORMITY

Manufacturer name	Optium Medikal Ltd.Sti.
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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 Numarası	GMDN
	OP 15	Monitor Chart, Wooden	8684325441605	
	OP 17	Folding Screen	8684325441612	42515
	OP 19	Examination Lamp	8684325441629	36843
	OP 24	Oxygen Tube Trolley, Large	8684325441636	
	HANGER	IV Stand, Mobile	8684325441025	36069
	HANGER SS	IV Stand, Mobile Stainless Steel	8684325441032	36069
	ES 11	Escabo, Single	8684325441797	42893
	ES 12	2 Step Escabo	8684325441803	42893
	NS 10	Negatoscope, Single	8684325441667	36488
	NS 20	Negatoscope, Double	8684325441674	36488
	NS 30	Negatoscope, Triple	8684325441681	36488
	NS 40	Negatoscope, LED, Quadruple	8684325441698	36488
	LT 27	Linen Trolley, Foldable	8684325441711	
	LT 28	Laundry Trolley, Clean-Dirty	8684325441728	
	LT 29	Laundry Trolley	8684325441735	
	DCB 11	Dresser Cupboard, Single	8684325441858	
	DCB 12	Dresser Cupboard, Wooden, Double	8684325441865	
Description and function designation:		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 :

