EU DECLARATION OF CONFORMITY

Manufacturer name	Optium Medikal Ltd.Sti.
Registered address	Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZIANTEP TURKEY
Telephone	+90 850 807 8462
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E-mail	info@optium.com.tr
Brand	optium TOUCHING LIVES
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	EMDN Code
EXAMY 1	Examination Couch with Cabinet	8684325440738	V080202
EXAMY 2	Examination Couch with Drawers	8684325440745	V080202
EXAMY 3	Examination Couch with Knockdown Construction	8684325440752	V080202
EXAMY 4	Examination Couch,Height Adjustment	8684325440769	V080202
EXAMY 5	Examination Couch, Height Adjustable	8684325440776	V080202
EXAMY 6	Examination Couch, Foldable	8684325440783	V080202
EXAMY 8	Pediatric Examination Couch	8684325442138	V080202

Description and function designation:	Examination couches intended for use in the standard care, including all applicable accessories.

WE HEREWITH DECLARE THAT THOSE ABOVE PRODUCTS WITH CE MARKING WHICH ARE MANUFACTURED BY OUR COMPANY ALL COMPLY WITH REGULATİON (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 :

optium MEDİKAL LTD. ŞTİ. Körkün Mah. Hidayet Cad. No: 23/1 OĞUZELİ/GAZİANTEP Tic.Sic.No: 56231 Mersis No:0644067549100001 SUBURCU V.D. : 644 067 54 91

Digitally signed by Grabazei Alexandru
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