Digitally signed by Bolea Petru
Date: 2022.10.04 09:02:40 EEST
Reason: MoldSign Signature
Location: Moldova

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 6284
Fax	+90 850 807 6284
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	8682897248011IN86

Products

REF	Product Name	UDI-DI Number	GMDN Code
IN-45	Electronic ICU Bed, Column Motors	8682897248004	34870
IN-44	Electronic ICU Bed, Column Motors	8682897248011	34870
IN-43	Electronic Low Bed, 4 Motors	8682897248028	34870
IN-42	Electronic ICU Bed, 4 Motors	8682897248035	34870
IN-41	Electronic ICU and Patient Care Bed, 4 Motors	8682897248042	34870
IN-32	Electronic Patient Care Bed, 3 Motors	8682897248059	34870
IN-22	Electronic Patient Care Bed, 2 Motors	8682897248066	34870

Description and function designation:	Electrically operated hospital bed intended for use in the standard care, acute care and intensive 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 EN ISO 14971:2012, EN 60601-2-38, and EN 60601-2-52:2010

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