


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)			
Products				
	REF	Product Name	UDI-DI Number	GMDN Code
	MOMENTUM	Functional Trauma Stretcher	8682897248219	35892
	EMERGEUM	Functional Emergency Stretcher	8682897248455	35892
	TRAVELLER	Patient Stretcher	8682897248462	35892
	ST 62	Hydraulic Patient Stretcher	8682897248479	35892
	ST 72	Patient Stretcher	8682897248486	35892
	OT TRANS	Operating Room Transfer Stretcher	8682897248493	35892
Description and function designation:	Patient transfer stretchers intended for use in the standard care and acute care, 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 Standards

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 :

