

Sertifika

certificate

CERTIFICATE of CONFORMITY

APPLICANT : Optium Medikal Ltd.Sti.

Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZİANTEP TURKEY

MANUFACTURER : Optium Medikal Ltd.Sti.

Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZİANTEP TURKEY

Product Name : MOMENTUM Functional Trauma Stretcher
EMERGEUM Functional Emergency Stretcher
TRAVELER Patient Stretcher
ST 72 Patient Stretcher
ST 62 Hydraulic Patient Stretcher
OT TRANS Operation Room Transfer Stretcher
STACKER SS Stackable Wheelchair, Stainless Steel
STACKER AL Stackable Wheelchair, Aluminum Const.
STACKER MRI Stackable Wheelchair, MRI Compatible
BD 18 Blood Drawing Chair
COSY BD Blood Drawing Chair
COSY PT Patient Transfer Chair

Trade mark : OPTIUM

Product Classification : Class I nonsterile, without measuring function

Applied Standard(s) : TS 6606, TS 6607, EN 60601-1:2006/A1:2013, EN 60601-1-6:2010,
EN ISO 14971:2019

Applied Directive(s) : 93/42/EEC Medical Device Directive

This certificate has been issued according to the voluntary application of the manufacturer. This certificate is valid only for the product(s) in above mentioned. This certificate confirms that the declaration of conformity which is prepared by manufacturer is available. It's manufacturer's sole responsibility to meet all the necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards or the mentioned product(s) before placing them on the market. It is the manufacturer's responsibility to comply a full technical file according to Annex VII of 93/42/EEC and the manufacturer is the responsible to take all necessary actions before affixing CE mark on the product(s). The technical file and test results of the above product have been checked and found in compliance with the above standards. This paper shows that this product has conformity with the related standard(s). The referred technical document(s) shows that the product complies with the essential requirements listed above EU Directive(s) and standard

Date of issue of this certificate : 09.02.2021

Expiry date : 08.02.2024

Certificate Number : 20.12.323-CE




Genel Müdür
General Manager