

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

Trade mark : OPTIUM

Product Name :

IN 45 Electronic ICU Bed, Column Motors
IN 44 Electronic ICU Bed, Columnar Motors
IN 43 Electronic ICU Bed, 4 Motors
IN 42 Electronic ICU Bed, 4 Motors
IN 41 Electronic ICU and Patient Care Bed, 4 Motors
IN 32 Electronic Patient Bed, 3 Motors
IN 22 Electronic Patient Bed, 2 Motors
IN 12 Electronic Patient Bed, Dual Motors
TI 46 Electronic ICU Bed, Column Motors
TI 44 Electronic ICU Bed, Column Motors
TI 42 Electronic ICU Bed, 4 Motors

TI 41 Electronic ICU and Patient Care Bed, 4 Motors
TI 32 Electronic Patient Bed, 3 Motors
TI 22 Electronic Patient Bed, 2 Motors
FU 45 Electronic ICU Bed, Column Motors
FU 43 Electronic ICU Bed, 4 Motors
FU 42 Electronic ICU Bed, 4 Motors
FU 32 Electronic Patient Bed, 3 Motors
FU 22 Electronic Patient Bed, 2 Motors
PE 41 Pediatric ICU Bed, 4 Motors
PE 32 Pediatric Ward Bed, 3 Motors
PE 22 Pediatric Ward Bed, 2 Motors
PF 32 Aluminum Pediatric Ward Bed, 3 Motors

Product Classification : Class I nonsterile, without measuring function

Applied Standard(s) : ISO 14971:2019, EN 60601-1, EN 60601-2-38, EN 60601-2-52:2010

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 : 20.12.321-CE



CE

Genel Müdür
General Manager