

Sertifika

certificate

CERTIFICATE of CONFORMITY

APPLICANT : Optium Medikal Ltd.Sti.

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

MANUFACTURER : Optium Medikal Ltd.Sti.

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

Product Name : ME 55 Hydraulic ICU and Patient Bed
ME 53 Hydraulic Patient Bed
ME 34 Manual ICU Bed, 3 Cranks
ME 24 Manual Patient Care Bed, 2 Cranks
ME 30 Manual ICU Bed, 3 Cranks
ME 20 Manual Patient Care Bed, 2 Cranks
ME 10 Manual Patient Care Bed, 1 Crank
ME 22 Manual Patient Care Bed, 2 Cranks, Foldable Legs
ME 11 Manual Patient Care Bed, 1 Crank, Foldable Legs
PM 10 Mechanical Pediatric Bed, Single adjustment
PM 20 Mechanical Pediatric Bed, 2 Cranks

Trade mark : OPTIUM

Product Classification : Class I nonsterile, without measuring function

Applied Standard(s) : TS 4271, EN 60601-1:2006/A1:2013, EN 60601-2-52:2010,
EN ISO 10993-5:2009, EN ISO 10993-10:2013 and 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 : 20.12.322-CE



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Genel Müdür
General Manager