

Sertifika

certificate

UYGUNLUK BELGESİ

CONFORMITY CERTIFICATE



APPLICANT : PROMA MEDİKAL LİMİTED ŞİRKETİ

BAŞVURAN

Başpınar (Organize) O.S.B. Mah. O.S.B. 5.BÖLGE 83548 NOLU CAD. No:6/1 Şehitkamil/ Gaziantep/Turkey

MANUFACTURER : PROMA MEDİKAL LİMİTED ŞİRKETİ

ÜRETİCİ

Başpınar (Organize) O.S.B. Mah. O.S.B. 5.BÖLGE 83548 NOLU CAD. No:6/1 Şehitkamil/ Gaziantep/Turkey

MODEL(S)/TYPE(S)/ MODEL ÇEŞİTLERİ :

AVANGARD 5000 – AVANGARD 4040 – CURA 5000 – CURA 4040 – CURA 4050 – CURA 4060 – CURA 3060 – CURA 3050 – CURA 2060 – CURA 2050 – CURA 2040 – SCH 4040 ELITE – SCH 4040 – SCH 4050 – SCH 4060 – SGH 4070 – SCH 4080 – SCH 5000 PJANE – SCH 3040 – SCH 3050 – SCH 3050 AL – SCH 3060 AL – SCH 2060 – SCH 2060 FORMEN – MT 01 – MT 02 – MT 03 – MT 04 – CURA 240 PL – CURA 240 DX – CURA 230 PL – CURA 230 DX – CURA 220 PL – CURA 220 DX – CURA 120 – DT 21 ELITE – DB 210 ELITE – MNB 200 – MNB 240 – MNB 230 – MNB 220 – MNB 210 – MNB 120 – MNB 100 – BLIZZ 1100 – PDB 1100 – PDB 1020 – PDA 1020 – PDA 3020 – PDB 1140 – PDB 1120 – PDB 1130 – PDB 1150 – CUNAS 11 – CUNAS 12 – CUNAS 13 – CUNAS 14 – CUNAS 15- ES 110 – CYCLONE – ES 140 – ST 27 – ST 120 – OT 140 – OT 150 – DIA 5 – DIA 4 – MPC 14 – BDC 12 – ENT 7 – ARTE – DT 21 M – SW 14 – DIA 4 ELEGANT – DT 21 ELEGANT – BDC 12 M – DT 21 M – DIA 485 M – ST 06 – ST 07 – WS 124 – SWS 103 – EXC 01 – EXC 02 – EXC 03 – EXC 04 – EXC 05 – EXC 06 – EXC 07 – OBT 162 – OBT 163 – OBT 161 – VOGN – BSC 331 – BSC 351 – BSC 321 – BSC 341 – BSC 311 – BSC 322 – BSC 352 – BSC 332 – BSOB 123 – FS 14 – AC 01 – AC 02 – AC 03 – EQ 07 – DC 101 – DC 102 – DC 103 – DC 104 – DC 105 – DC 106 – DC 107 – DC 108 – DC 109 – DC 110 – NT 110 – NT 120 – NT 130 – MM 01 – MM 02 – PK 01 – PK 02

PRODUCT NAME / ÜRÜN ADI :

Elektronik – Manuel Hastane Koltuk ve Masaları / Electronic – Manual Hospital Chairs & Tables

Elektronik-Manuel pediatrik yatak/ Electronic-Manual pediatric bed

Çok Fonksiyonlu Hastane Sedyeleri / Multifunctional Hospital Stretcher

Elektronik yoğun bakım yatağı / Electronic ICU bed

Elektronik-Manuel hasta karyolası/ Electronic-Manual ward bed

Trade Mark/ Ticari Marka : SCHRÖDER HEALTH PROJECTS

Applied standard(s) : - EN 60601-2-41:2009 - EN 60601-1-2:2015 - EN 60601-1:2006 +A1:2013

Uygulanan Standartlar - TS EN 60601-1 - EN 60601-2-52:2010

Directive(s)/ Yönetmelikler : 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)

Date of issue of this certificate : 15.04.2021

Bu sertifikanın yayın tarihi

Expiry Date : 14.04.2023

Geçerlilik tarihi

Certificate Number : 18.11.310-CE

Sertifika No




Genel Müdür
General Manager

EC DECLARATION OF CONFORMITY

Date of issue: 01.01.2022

Conformity declaration issued by:

The Legal and Actual Manufacturer	Proma medikal LTD. ŞTİ.
Registered address	Başpınar (Organize) O.S.B. Mah. O.S.B. 5.BÖLGE 83548 NOLU CAD. No:6/1 Şehitkamil/Gaziantep-TURKEY
Telephone	+90 342 230 1583 / +90 850 202 7750
Fax	+90 342 230 1583
E-mail	export@schroderhealth.de
Brand	 ELECTRONIC WARD BED, 3 MOTORS - CURA 3060
Description and function designation:	Using at hospitals including all applicable accessories.
Classification of the product as the medical device:	Class I nonsterile

A) Declaration

I declare that the said products are safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

B) Fulfilled technical requirements

These products' characteristics comply with the technical parameters related to it and stated in MDR - 2017/745 as amended , which stipulates the technical parameters for healthcare products.

C) Means of assessing conformity

Conformity was assessed by the procedure stated MDR - 2017/745

D) Used standards

The said products fulfills the requirements of these harmonized technical standards which were used for assessing of conformity: EN980, EN1041:2008, EN60601-1:2006+A1:2013, EN60601-1-2:2015, EN60601-2-41:2009, TS 6606 – TS 6607, - IEC 60601-2- 52:2009

CEO – Barış Özbiçki

PROMA MEDİKAL LTD. ŞTİ.
Tel:0 342 230 15 83 Fax:0 342 230 15 83
Sımsıkçı Mah. Med. Gaziantep Yolu Cd. No:3
Şahinbey V.D.033 041 889072 Şic. No:29782
ŞAHİNBİY/GAZİANTEP

Client Name and address

Müşteri ismi ve adresi

**PROMA MEDİKAL LİMİTED ŞİRKETİ**
PROMA MEDİKAL LTD. ŞTİ.BAŞPINAR (ORGANİZE) O.S.B MAHALLESİ O.S.B 5. BÖLGE
83548 NOLU CAD. NO:6/1/0 ŞEHİTKAMİL/GAZİANTEP

Standard

Standard

ISO 14001:2015Çevre Yönetim Sistemi
Environmental Management System
UMWELTSMANAGEMENTSYSTEM

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

HASTANE MOBİLYALARI VE EKİPMANLARI ÜRETİMİ VE SATIŞI

MANUFACTURING AND SELLING OF HOSPITAL FURNITURES AND EQUIPMENTS

DER VERKAUF UND DIE HERSTELLUNG DER GERÄTE UND MOBEL DES KRANKENHAUSES

EA/Category Code: 23

İlk Yayın Tarihi/Initial issue date/Das Initialausgabedatum: 29.Jun.2020

Bu sertifikanın yayın tarihi/Issue date of this certificate/Ausgabedatum dieses Zertifikat : 27.Jul.2021

Bu sertifikanın geçerlilik tarihi/Validity of this certificate/Gültigkeitsdatum dieses Zertifikats: 28.Jun.2022

Yeniden belgelendirme tarihi/Recertification date/Wiederzertifizierungsdatum: 28.Jun.2023

Sertifika Numarası/Certificate No/Zertifikatsnummer: 20.04.316-EM

General Manager

To verify the validity of this certificate please visit: www.inspect.com.tr
Bu sertifikanın geçerliliğini kontrol etmek için lütfen www.inspect.com.tr'yi ziyaret ediniz

The validity of this certificate is depend on the success of surveillance assessments
Bu belgenin geçerliliği ara denetimlerin başarılı olmasına bağlıdır.



CURA® 3060 / 3 Functions Electric Bed



An Electric patient bed CURA 3060 powered by double motors provides patient safety, bacteriological protection and patient comfort during a hospital stay.

Unique modern designed CURA 3060 is a high quality medical bed, adjustable height will be the best choice for patient care. Its simply design meets all standard functions for patient care both in ward hospital or home care.

Meet with the CURA 3060 improve your patients comfort, safety and satisfaction.

Features and benefits

ABS side rails can be activated using one hand and feature a smooth, rapid self-lowering mechanism allowing for quick access to patients

Stable support is provided during bed exit via an Ergonomically placed side egress grip handle

Intuitive bed controls electronic motors back, foot and height adjustments.

Back adjustment : 70 degree , foot 40 degree capability.

Head and foot panels easy remove with knock for patient safe.

External dimensions : 104x220 cm

Height adjustment: 45 - 78 cm.

Low height indicator warns the caregiver if the bed is not in the lowest position, contributing to a safer patient environment

Mattress, antibacterial, water proof breathable.

Mattress platform, 4 sections.

Iv pole and lifting pole socket at 4 corner application and located protection bumpers.

150 mm lockable and swivel castors.

Nano technology electrostatic powder coating technique painting.



Additional standard features

- Bilateral Mechanical CPR lever
- 6 attachment points for patient restraints
- Lifting/IV pole holders
- Bilateral accessory holder
- Cord holder
- Adjustable mattress retainers
- Metallic silver color
- Removable endboards
- Line-of-site backrest and Trendelenburg indicators
- One-Touch Side Egress positioning
- Central brake
- Vertical oxygen tube holder.



The CURA bed is intended for use in intensive, acute and ambulatory care settings for patients with a weight ≥ 40 kg, height ≥ 146 cm and BMI ≥ 17 .

Class I

Manufacturer: PROMA MEDIKAL LTD STI , Baspınar OSB 5. Bolge 83548 Gaziantep/Turkey

This medical device is a regulated health product which, pursuant to such regulation bears a CE mark. Schröder recommends that you carefully read the detailed instructions for safe and proper use included in the documents accompanying the medical devices. The personnel of healthcare establishments are responsible for the proper use and maintenance of these medical devices.

schröder reserves the right to make changes without notice in design, specifications and models. The only warranty schröder makes is the express written warranty extended on the sale or rental of its products.

2020 schröder health projects ALL RIGHTS RESERVED.

Not all products/options are available in all countries.

For further information about our products and services, please contact your local Schröder representative or visit our webpage:

www.schröderhealth.de



Schröder™