

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marajul CE
Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul **AELO GRUP SRL**, cu sediul **mun.Chișinău, str.Mitropolit Petru
Movila 23/5, ap.6,**
tel./fax: **+373 61 033 993/022 60 14 91**, e-mail: **aelogrup@gmail.com**,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a:

WANS 4040 HOSPITAL ELECTRIC BED, 4 MOTORS, Schroder Medikal

Se anexează următoarele acte:
ISO;Decalaratie de conformitate;Brosura,

Data 20.06.2023

Semnătura _____



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Aelo Grup SRL,

cu sediul în: mun.Chișinău, str.Mitropolit Petru Movila 23/5, ap,6

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

WANS 4060 HOSPITAL ELECTRIC BED, 4 MOTORS, Schroder Medikal

Sunt autentice și corespund realității.

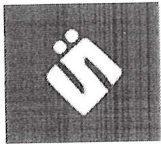
Cobzari -Țurcan Rodica
Administrator

Semnătura



Data 20.06.2023





Schröder™

EC DECLARATION OF CONFORMITY

Date of issue: 03.04.2023

Conformity declaration issued by:

The Legal and Actual
Manufacturer

Schroder Medikal Ticaret Anonim Şirketi

Registered address

Başpınar (Organize) O.S.B Mah. O.S.B 5. Bölge 83548 Nolu Cad. No:6/1,
Sehitkamil Gaziantep Türkiye

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E-mail

info@schroderhealth.de

Brand



Schröder

Products

PDB-1130 PEDIATRIC BED 2 MOTORS, PDB-1120 PEDIATRIC BED 2 MOTORS, PDB-1140 PEDIATRIC BED 3 MOTORS, BC-11 BABY COTE, BC-12 BABY COTE WITH CABINET, MT-04 VISCOELASTIC MATTRESS, MT-01 FOAM MATTRESS, MT-02 FOAM MATTRESS SOFT SENSE, BSC-311 BEDSIDE CABINET, BSC-341 BEDSIDE CABINET, BSC-351 BEDSIDE CABINET, BSC-331 BEDSIDE CABINET, BSC-321 BEDSIDE CABINET, BSC-352 BEDSIDE CABINET, BSC-332 BEDSIDE CABINET, BSC-322 BEDSIDE CABINET, OBT-161 OVERBED TABLE, OBT-162 OVERBED TABLE, OBT-160 OVERBED TABLE, OBT-163 OVERBED TABLE, AC-03 ATTENDANT COUCH, AC-02 ATTENDANT COUCH, AC-01 ATTENDANT COUCH WITH CASTORS, DT-21 ELITE DELIVERY BED, ES-110 FUNCTIONAL EMERGENCY STRETCHER, ES-110 CYCLONE TRAUMA STRETCHER, ST-120 GENERAL PURPOSE PATIENT STRETCHER, OT-140 OPERATION ROOM TRANSFER STRETCHER, DT-21 ELECTRONIC DELIVERY TABLE 3 MOTORS, DIA-2 ELECTRONIC DIALYSIS CHAIR 2 MOTORS, DIA-4 ELECTRONIC DIALYSIS CHAIR 4 MOTORS, MPC-14 ELECTRONIC BLOOD TRANSFUSION CHAIR 4 MOTORS, ENT-7 ELECTRONIC ENT CHAIR 4 MOTORS, BDC-12 ELECTRONIC BLOOD DRAWING CHAIR 2 MOTORS, ARTE FUNCTIONAL PATIENT TRANSFER CHAIR, SW-14 SPACE SAVER STACKABLE WHEELCHAIR SS, EXC-01 EXAMINATION COUCH WITH DRAWERS AND CABINET, EXC-02 EXAMINATION COUCH WITH 3 DRAWERS, EXC-04 EXAMINATION COUCH, EXC-05 EXAMINATION COUCH, EXC-06 EXAMINATION COUCH FOLDABLE, EXC-07 PEDIATRIC EXAMINATION COUCH, WS-122 WAITING ROOM SEAT DOUBLE, WS-123 WAITING ROOM SEAT TRIPLE, WS-124 WAITING ROOM SEAT TRIPLE, WS-125 WAITING ROOM SEAT DOUBLE, WS-132 WAITING ROOM SEAT DOUBLE, WS-133 WAITING ROOM SEAT TRIPLE, WS-143 WAITING ROOM SEAT TRIPLE, WS-151 WAITING ROOM SEAT SINGLE, WS-152 WAITING ROOM SEAT DOUBLE, WS-153 WAITING ROOM SEAT TRIPLE, WS-161 WAITING ROOM SEAT SINGLE, WS-162 WAITING ROOM SEAT DOUBLE, WS-163 WAITING ROOM SEAT TRIPLE, WS-171 WAITING ROOM SEAT SINGLE, WS-172 WAITING ROOM SEAT DOUBLE, WS-173 WAITING ROOM SEAT TRIPLE, SWS-101 WAITING ROOM SEAT SINGLE, SWS-102 WAITING ROOM SEAT DOUBLE, SWS-103 WAITING ROOM SEAT TRIPLE, SWS-102-S WAITING ROOM SEAT DOUBLE WITH MIDDLE TABLE, SWS-111 WAITING ROOM SEAT SINGLE, SWS-112 WAITING ROOM SEAT DOUBLE, SWS-113 WAITING ROOM SEAT TRIPLE, ST-06 STOOL, ST-07 STOOL WITH BACKREST, IVP-06 IV STAND MOBILE, IVP-07 IV STAND MOBILE SS, EQ-05 ESCABO DOUBLE, EQ-07 INSTRUMENT AND MEDICINE CABINET, NT-110 NEGATOSCOPE SINGLE SLIM, NT-120 NEGATOSCOPE DOUBLE SLIM, NT-130 NEGATOSCOPE TRIPLE SLIM, FS-14 FOLDING SCREEN METAL, DC-101 LOCKER SINGLE, DC-102 LOCKER DOUBLE, DC-103 SHOWCASE, DC-104 LOCKER QUADRUPLE, DC-105 STEEL LOCKER DOUBLE, DC-106 STEEL LOCKER SINGLE, DC-107 STEEL LOCKER DOUBLE, DC-108 STEEL LOCKER TRIPLE, DC-109 STEEL LOCKER, QUADRUPLE, DC-110 STEEL LOCKER SEXTETTE, SSV-50-T SINGLE BAY SCRUB SINK WITH FOTOCELL, SSV-50-D, SINGLE BAY SCRUB SINK WITH KNEE OPERATED, SSV-130-D DOUBLE BAY SCRUB SINK WITH KNEE OPERATED, SSV-130-M DOUBLE BAY SCRUB SINK WITH FOTOCELL, SSV-205-F TRIPLE BAY SCRUB SINK WITH FOTOCELL, SSV-205-D TRIPLE BAY SCRUB SINK WITH KNEE OPERATED, SSD-01 OPERATION ROOM CUPBOARD, SSD-02 OPERATION ROOM CUPBOARD, SSM-01 OPERATION ROOM WORKDESK, SSM-02 OPERATION ROOM WORKDESK, SSW-01 TOOLS WASHING SINK WITH TABLE, SSW-02 TOOLS WASHING SINK, SSW-03 TOOLS WASHING SINK WITH TABLE, ESB-01 ESCABO, SINGLE, ESB-02 ESCABO DOUBLE, SST-01 INSTRUMENT TROLLEY 2 SHELVES, SST-02 INSTRUMENT TROLLEY 3 SHELVES, MM-01 MAYO TABLE HYDRAULIC, MM-02 MAYO TABLE MANUAL, SOT-01 AUTOPSY TABLE WITH SINK, SOT-02 AUTOPSY TABLE HEIGHT ADJUSTABLE, SMU-02 MORTUARY UNIT DOUBLE, PK-01 SINGLE BOWL STAND, PK-02 DOUBLE BOWL STAND, SDT-01 DRESSING TROLLEY, AVANGARD 5000 HOSPITAL ELECTRIC BED 4 MOTORS, ALUMINUM BASE, AVANGARD 4040 HOSPITAL ELECTRIC BED 4 MOTORS, ALUMINUM BASE, AVANGARD 3050 HOSPITAL ELECTRIC BED 3 MOTORS, ALUMINUM BASE, AVANGARD 2060 HOSPITAL ELECTRIC BED 2 MOTORS, ALUMINUM BASE, CURA 5000 HOSPITAL ELECTRIC BED, 5 MOTORS, CURA 4060 HOSPITAL ELECTRIC BED, 4 MOTORS, CURA 4050 HOSPITAL ELECTRIC BED, 4 MOTORS, CURA 4040 HOSPITAL ELECTRIC BED, 4 MOTORS, CURA 3060 HOSPITAL ELECTRIC BED, 3 MOTORS, CURA 3050 HOSPITAL ELECTRIC BED, 3 MOTORS, CURA 2060 HOSPITAL ELECTRIC BED, 2 MOTORS, CURA 2050 HOSPITAL ELECTRIC BED, 2 MOTORS, CURA 2040 HOSPITAL ELECTRIC BED, 2 MOTORS, CURA 240 DX MECHANICAL OPERATED HOSPITAL BED, 4 CRANKS, CURA 240 PL MECHANICAL HOSPITAL BED, 4 CRANKS, CURA 230 PL MECHANICAL OPERATED HOSPITAL BED, 3 CRANKS, CURA 220 PL PARALLEL MECHANICAL OPERATED HOSPITAL BED, 2 CRANKS, CURA 220 DX PLASTIC MECHANICAL OPERATED HOSPITAL BED, 2 CRANKS, CURA 120 PL MECHANICAL OPERATED HOSPITAL BED, 1 CRANK, PDB 1130 PEDIATRIC HOSPITAL BED, 3 MOTORISED, PDB 1120 PEDIATRIC HOSPITAL BED, 2 ADJUSTMENTS, PDB 1100 PEDIATRIC HOSPITAL BED, 2 MOTORISED, PDB 1020 PEDIATRIC HOSPITAL BED, 2 MOTORISED, PDA 3020 PEDIATRIC HOSPITAL BED, 3 MOTORISED ALUMINUM BASE,





SchröderTM

PDA 1020 PEDIATRIC HOSPITAL BED, 2 MOTORISED ALUMINUM BASE, CUNAS 15 HOSPITAL CRIB & CABINET, CUNAS 14 HOSPITAL CRIB & CABINET, CUNAS 12 STACKABLE HOSPITAL CRIB, CUNAS 11 HOSPITAL CRIB, BLIZZ 1100 ELECTRICAL OBSTETRIC / DELIVERY BED, BSOB 123 BEDSIDE CABINET WITH OVERBED TABLE, METAL, BSOB 123 BEDSIDE CABINET WITH OVERBED TABLE, ABS, CYCLONE PROCEDURAL STRETCHER, CYCLONE TRANSPORT STRETCHER, CYCLONE TRAUMA STRETCHER, VOGN PROCEDURE CART, VOGN TREATMENT CART, VOGN ANESTHESIA CART, VOGN EMERGENCY CART, EMC 01 EMERGENCY CART, EMC 02 ANESTHESIA CART, EMC 03 TREATMENT CART, WANS 5000 HOSPITAL ELECTRIC BED, 4 MOTORS, WANS 4040 HOSPITAL ELECTRIC BED, 4 MOTORS, WANS 4050 HOSPITAL ELECTRIC BED, 4 MOTORS, WANS 4060 HOSPITAL ELECTRIC BED, 4 MOTORS, WANS 3060 HOSPITAL ELECTRIC BED, 3 MOTORS, WANS 3050 HOSPITAL ELECTRIC BED, 3 MOTORS, WANS 2060 HOSPITAL ELECTRIC BED,

Description and function designation:

Using at hospitals including all applicable accessories.

Classification of the product as the medical device:

Class I nonsterile, without measuring function

A) Declaration

We 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 MDD 93/42/EC as amended, which stipulates the technical parameters for healthcare products.

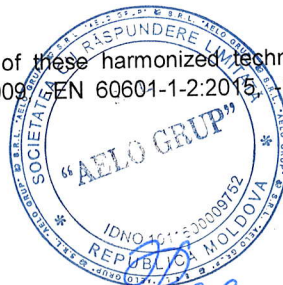
C) Means of assessing conformity

Conformity was assessed by the procedure stated MDD 93/42/EEC

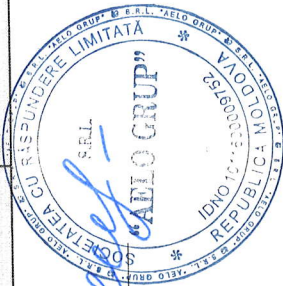
D) Used standards

The said products fulfill the requirements of these harmonized technical standards which were used for assessing of conformity: -EN60601-2-41:2009, -EN 60601-1-2:2015, -EN 60601-1:2006 +A1:2013, -TS EN 60601-1, -EN 60601-2-52:2010

SCHRÖDER MEDICAL TIC. A.Ş.
Tel. 0350 202 77 50 • e-mail: finanse@schroderhealth.de
Başpınar (Orneştina) Şişli Hastanesi O.s.b. Ş. Bölge
83548 Nohy 60 No.8/1 Şişli Hastanesi/GAZİANTEP
Ticaret Sicil No: 69216
Şişli Hastanesi V.D. 757 098 8720



Nr.	Catalog number (reference)*	Generic name (device name)	Commercial name (brand)*	Model	Number GMDN*
1	HOSPITAL ELECTRIC BED, 4 MOTORS	HOSPITAL ELECTRIC BED, 4 MOTORS	Schroder Medikal Ticaret Anonim Şirketi	WANS 4040	34870



Sernat Aelo Grup SRL
Administrator Ceban Iurcan Rodica

Manufacturer's Authorization

We, Schroder Medikal Ticaret A.S, based in at Baspinar Mah. 5. Organize San. Bol. 83548 Nolu Cad. No:6 Sehitkamil Gaziantep Türkiye, assign Aelo Grup SRL, based in Str Mitropolit Petru Movilă 23/5 ap.3, Chisinau MD -2004, Moldova, as authorized representative in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Gaziantep Date: 19.06.2023

SCHRÖDER MEDİKAL TİC. A.Ş.
Tel.: 0850 202 77 50 e-mail: finans@schroderhealth.de
Baspınar (Organize) OSB Mahallesi O.s.b. 5. Bölge
83548 Nolu Cad. No:6/1 Sehitkamil/GAZİANTEP
Ticaret Sicil No: 69216
Sehitkamil V.D. 757 098 8720

Name: Furkan Gürünlü

Title: Area Sales Executive



SCHRÖDER HEALTH PROJECTS
Schroder Medikal Tic. A.ş

BASPINAR MAH. 5. O.S.B 83548 NOLU CAD NO:6/1/0 SEHITKAMIL GAZİANTEP

Ph : +90 850 202 77 50 Fax: +90 342 230 15 83 www.schroder.com.tr info@schroder.com.tr

Factory : BASPINAR (ORGANIZE) OSB MAH. OSB 5.BOLGE 83548 NO CAD. NO:6 SEHITKAMIL GAZİANTEP TURKEY



inspect

Certificate

Sertifika

Client Name and address

Müşteri ismi ve adresi

SCHRODER MEDİKAL TİC. A.Ş.

PROMA MEDİKAL LİMİTED ŞİRKETİ

PROMA MEDİKAL LTD. ŞTİ.

SCHRÖDER HEALTH PROJECTS

BAŞPINAR (ORGANİZE) O.S.B MAHALLESİ O.S.B 5. BÖLGE
83548 NOLU CAD. NO:6/1/0 ŞEHİTKAMİL/GAZİANTEP

Standard

Standard

ISO 13485:2016

Kalite Yönetim sistemi - Medikal Cihaz
Medical Devices - Quality Management Systems
QUALITÄTSMANAGEMENTSYSTEM-Medizinische Geräte

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: A

İlk Yayın Tarihi/Initial issue date/Das Initialausgabedatum: 27.Jul.2021

Bu sertifikanın yayın tarihi/Issue date of this certificate/Ausgabedatum dieses Zertifikat : 15.Jun.2022

Bu sertifikanın geçerlilik tarihi/Validity of this certificate/Gültigkeitsdatum dieses Zertifikats: 26.Jul.2023

Yeniden belgelendirme tarihi/Recertification date/Wiederzertifizierungsdatum: 26.Jul.2024

Sertifika Numarası/Certificate No/Zertifikatsnummer: 21.04.341-MD



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.

INSPECT Uluslararası Belgelendirme ve Gözetim Hiz. Tic. Ltd. Şti. / TURKEY
www.inspect.com.tr - Belge periyodu 3 yıldır. / Certificate period is 3 years.



inspect

Certificate
Sertifika

Client Name and address

Müşteri ismi ve adresi

SCHRODER MEDİKAL TİC. A.Ş.

PROMA MEDİKAL LİMİTED ŞİRKETİ
PROMA MEDİKAL LTD. ŞTİ.

SCHRÖDER HEALTH PROJECTS

BAŞPINAR (ORGANİZE) O.S.B MAHALLESİ O.S.B 5. BÖLGE
83548 NOLU CAD. NO:6/1/0 ŞEHİTKAMİL/GAZİANTEP

Standard

Standard

ISO 9001:2015

Kalite Yönetim Sistemi
Quality Management System
QUALITÄTSMANAGEMENTSYSTEM

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: 15.Jun.2022

Bu sertifikanın yayın tarihi/Issue date of this certificate/Ausgabedatum dieses Zertifikat : 15.Jun.2022

Bu sertifikanın geçerlilik tarihi/Validity of this certificate/Gültigkeitsdatum dieses Zertifikats: 14.Jun.2023

Yeniden belgelendirme tarihi/Recertification date/Wiederzertifizierungsdatum: 14.Jun.2025

Sertifika Numarası/Certificate No/Zertifikatsnummer: 22.05.301-QM



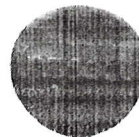
To verify the validity of this certificate please visit: www.inspect.com.tr

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The validity of this certificate is depend on the success of surveillance assessments

Bu belgenin geçerliliği ara denetimlerin başarılı olmasına bağlıdır.

INSPECT Uluslararası Belgelendirme ve Gözetim Hiz. Tic. Ltd. Şti. / TURKEY
www.inspect.com.tr - Belge periyodu 3 yıldır. / Certificate period is 3 years.



IAS
ACCREDITED
Management System
Certification Body
MSCB-148