

(AB) 2017/745



AT DECLARATION OF CONFORMITY

DOC. NO: FR.KG.32

REV. NO :00

REV. DATE : -

PUBLISH DATE: 29.07.2021

PAGE NO: 1/7

Gökler Mobilya Medikal Ve Sağlık Hizmetleri Gıda Maddeler İnşaat Nakliye İmalat Montaj Pazarlama İthalat İhracat Sanayi Ticaret Anonim Şirketi

Organize Sanayi Bölgesi
1.Kısım 1.Cadde No: 7-8
Merkez/SİVAS
TÜRKİYE

Declare under our sole responsibility that the product,

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
MANUEL PATENT BED	NITRO HB 1110	1	869925869054TV
	NITRO HB 1110 S		869925869263U8
	NITRO HB 1120		869925869053TT
	NITRO HB 1130		869925869052TR
	NITRO HB 1310		869925869048U2
	NITRO HB 1410		869925869045TU
	NITRO HB 1420		869925869044TS
	NITRO HB 1430		869925869043TQ
	NITRO HB 1330		869925869046TW
	NITRO HB 1320		869925869047TY
	NITRO HB 1230		869925869049U4
	NITRO HB 1220		869925869050TM
	NITRO HB 1210		869925869051TP
	NITRO HBY 1110 NEW		869925869247UA

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
ELECTRICAL PATIENT BED	NITRO HB 2110	1	869925869042TN
	NITRO HB 2220		869925869038TX
	NITRO HB 2230		869925869037TV
	NITRO HB 2310		869925869036TT
	NITRO HB 2320		869925869035TR
	NITRO HB 2330		869925869034TP
	NITRO HB 2210		869925869039TZ
	NITRO HB 2130		869925869040TJ
	NITRO HB 2120		869925869041TL
	NITRO HB 3110		869925869033TM
	NITRO HB 3120		869925869032TK
	NITRO HB 3140		869925869214TT
	NITRO HB 3150		869925869215TV
	NITRO HB 3160		869925869216TX
	NITRO HB 3220		869925869029TW
	NITRO HB 3210		869925869030TF
	NITRO HB 3130		869925869031TH
	NITRO HB 3310		869925869027TS

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ELECTRICAL
PATIENT BED

1

NITRO HB 3320
NITRO HB 3330
NITRO HB 3230
NITRO HB 3340
NITRO HB 3350
NITRO HB 3360
NITRO HB 4000
NITRO HB 4110
NITRO HB 4120
NITRO HB 4130
NITRO HB 4210
NITRO HB 4220
NITRO HB 4230
NITRO HB 4310
NITRO HB 4320
NITRO HB 4330
NITRO HB 4410
NITRO HB 4420
NITRO HB 4430
NITRO HB 5110
NITRO HB 5120
NITRO HB 5130
NITRO HB 5210
NITRO HB 5220
NITRO HB 5230
NITRO HB 5240
NITRO HB 5310
NITRO HB 5320
NITRO HB 5330
NITRO HB 6000
NITRO HB 6210
NITRO HB 6220
NITRO HB 6230
NITRO HB 6240
NITRO HB 6250
NITRO HB 6260
NITRO HB 6410
NITRO HB 6420
NITRO HB 6430
NITRO HB 6440
NITRO HB 6450
NITRO HB 6460
NITRO HB 6610
NITRO HB 6620
NITRO HB 6630
NITRO HB 6640
NITRO HB 6650

869925869026TQ
869925869025TN
869925869028TU
869925869217TZ
869925869218U3
869925869219U5
869925869024TL
869925869023TJ
869925869022TG
869925869021TE
869925869020TC
869925869019TT
869925869018TR
869925869017TP
869925869016TM
869925869015TK
869925869014TH
869925869013TF
869925869012TD
869925869011TB
869925869010T9
869925869009TQ
869925869008TN
869925869007TL
869925869006TJ
869925869005TG
869925869004TE
869925869003TC
869925869002TA
869925869131TN
869925869098UH
869925869099UK
869925869100TB
869925869101TD
869925869102TF
869925869103TH
869925869119TY
869925869120TH
869925869121TK
869925869122TM
869925869123TP
869925869124TR
869925869125TT
869925869126TV
869925869127TX
869925869128TZ
869925869129U3

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NITRO HB 6660
NITRO HB 7000
NITRO HB 7000W
NITRO HB 7210
NITRO HB 7220
NITRO HB 7230
NITRO HB 7240
NITRO HB 7250
NITRO HB 7250 S
NITRO HB 7260
NITRO HB 7260 FUR
NITRO HB 7410
NITRO HB 7420
NITRO HB 7430
NITRO HB 7440
NITRO HB 7450
NITRO HB 7460
NITRO HB 7610
NITRO HB 7620
NITRO HB 7630
NITRO HB 7640
NITRO HB 7650
NITRO HB 7660
NITRO HB 8000
NITRO HB 8000 B
NITRO HB 8000 D
NITRO HB 8000 T
NITRO HB 8120
NITRO HB 8130
NITRO HB 8133
NITRO HB 8140
NITRO HB 8140 ELC
NITRO HB 8140 C
NITRO HB 8150
NITRO HB 2330 N
NITRO HB 3110 N
NITRO HB 3120 N
NITRO HB 3320 N
NITRO HB 3330 N
NITRO HB 4130 N
NITRO HB 4310 N
NITRO HB 4320 N
NITRO HB 4410 N
NITRO HB 5130 N
NITRO HB 5230 N
NITRO HB 6260 N
NITRO HBY 5220 NEW

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869925869132TQ
869925869260U2
869925869133TS
869925869134TU
869925869135TW
869925869136TY
869925869248UC
869925869250TX
869925869138U4
869925869261U4
869925869139U6
869925869140TP
869925869141TR
869925869142TT
869925869143TV
869925869144TX
869925869145TZ
869925869146U3
869925869147U5
869925869148U7
869925869149U9
869925869150TS
869925869226U2
869925869252U3
869925869259UH
869925869255U9
869925869227U4
869925869228U6
869925869234TZ
869925869229U8
869925869264UA
869925869251TZ
869925869257UD
869925869196UJ
869925869197UL
869925869198UN
869925869199UQ
869925869200TG
869925869201TJ
869925869202TL
869925869203TN
869925869204TQ
869925869205TS
869925869206TU
869925869207TW
869925869236U5

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PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
PEDIATRIC PATIENT BED	NITRO HB 1130 P	1	869925869191U8
	NITRO HB 2130 P		869925869190U6
	NITRO HB 2420 P		869925869071TV
	NITRO HB 2430 P		869925869072TX
	NITRO HB 3420 P		869925869073TZ
	NITRO HB 3430 P		869925869074U3
	NITRO HB 4420 P		869925869075U5
	NITRO HB 4430 P		869925869076U7

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
BABY COT	BK 01	1	869925869109TV
	BK 02		869925869110TE

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
EXAMINATION TABLES	NTHM 093	1	869925869184UB
	NTHM 094		869925869185UD
	NTHM 095		869925869186UF
	NTHM 096		869925869187UH
	NTHM 097		869925869080TW
	NTHM 098		869925869081TY
	CARET 501		869925869065U2
	CARET 502		869925869066U4
	CARET 503		869925869067U6

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
WHEELCHAIRS/ TROLLEYS	NTS X5	1	869925869095UB
	NTS X6		869925869096UD
	NTS X7		869925869097UF
	NTS X8		869925869113TL
	NTS X9		869925869114TN
	NTS X10		869925869115TQ
	NTS X11		869925869158UA
	NTS X12		869925869159UC
	NTS X13		869925869160TV
	NTS X14		869925869161TX
	NTS X15		869925869162TZ
	NTY X05		869925869238U9
	NTY X07		869925869237U7

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PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
GYNEOLOGICAL EXAMINATION AND DELIVERY TABLES	JMM 01	1	869925869070TT
	JMM 02		869925869093U7
	JMM 03		869925869094U9
	JMM 04 (EVA)		869925869104TK
	JMM 05		869925869188UK
	JMM 06		869925869189UM
	JMM 01 N		869925869208TY
	JMYM 002		869925869245U6
	JMM SANTE 02		869925869253U5

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
STRETCHERS	NTCR SD01	1	869925869174U8
	NTCR SD02		869925869175UA
	NTCR SD03		869925869176UC
	NTCR SD04		869925869177UE
	NTCR SD05		869925869178UG
	NTCR SD06		869925869179UJ
	NTCR SD07		869925869180U3
	NTCR SD08		869925869181U5
	NTCR SD09		869925869182U7
	NTCR SD10		869925869183U9
	NTCR SD11		869925869195UG
	NTCR SD12		869925869220TN
	NTCR SD13		869925869231TT
	NTCR SD14		869925869235U3
	NTCR SD15		869925869258UF
	NTCR SD14 DRIVE		869925869256UB
	NTCY SD01 NEW		869925869249UE
	NTCY SD08 NEW		869925869246U8
	NHS 860 (NT Q7)		869925869092U5
	NHS 880 (PEDIATRİK)		869925869106TP

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
MEDICINE AND TREATMENT CARTS	NTHM 112	1	869925869077U9
	NTHM 113		869925869078UB
	NTHM 114		869925869116TS
	NTHM 115		869925869117TU
	NTHM 116		869925869118TW
	NTHM 117		869925869151TU
	NTHM 118		869925869152TW
	NTHM 119		869925869153TY
	NTHM 120		869925869154U2
	NTİ 102 (NTİ 2102)		869925869240TU

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	NTİ 103 (NTİ 2103)		869925869241TW
	NTİ 104 (NTİ 2104)		869925869242TY
	NTİ 105 (NTİ 2105)		869925869243U2
	NTİ 106 (NTİ 2106)		869925869244U4
	NTİ 2108B		869925869254U7

SAYFA NO: 6/7

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
MEDICAL CHAIRS	NHS 870	1	869925869105TM
	NHS 900		869925869192UA
	NHS 901		869925869193UC
	NHS 902		869925869194UE
	NHS 903		869925869209U2
	NHS 904		869925869210TK
	NHS 905		869925869211TM
	NHS 906		869925869212TP
	NCRY 1002 NEW		869925869239UB
	DLCE 3914		869925869262U6

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
PATIENT LIFT	HKL 01	1	869925869233TX

PRODUCT	PRODUCT CODE	CLASS	UDI-DI NO
IV POLE	NTHM 103	1	869925869079UD
	NTHM 104		869925869064TY

omplied with the procedures defined by the European parliament and council directive **(EU) 2017/745 Annex IV Declaration of Conformity (Annex II and Annex III)** in accordance with the Medicinal Product law.

This declaration is valid for products placed on the market as of the date of release. Any unauthorized modifications to the device will invalidate this statement.

The products are OTHER **(without sterilization and measurable properties)** Class I category products.

Standards	Standard Descriptions
EN 60601-1:2006/A1:2013 AMD 12 2014 (IEC 60601-1:2005 + A1.2012)	Medical electrical equipment - Part 1: General requirements for basic safety and basic performance

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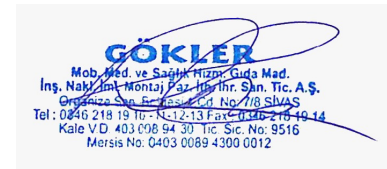
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EN 60601-1-2 :2015 (IEC 60601-1-2 :2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and basic performance - Warranty Standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6 :2010 AMD 1 2015 (IEC 60601-1-6 :2010, AMD 1:2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and basic performance - Coverage Standard - Availability
EN 62366:2008 AMD 1 2015 (IEC 62366:2007+A 1 2014)	Medical devices - Application of usability engineering to medical devices
EN ISO 14971 :2012 (ISO 14971 :2007, corr. 2007)	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 (ISO 15223-1: 2016)	Graphic Symbols for use in labeling medical devices
TS EN 60601-2-52:2010/AC:2011	"Medical electrical equipment - Part 2-52: Special requirements for basic safety and basic performance of medical beds"
TS EN 12183	Manual wheelchairs - Requirements and test methods
TS 6606/T3	Hospital-Use for Stretchers
TS 5541/T1	Patient Exam Chair-General Use
TS 4271/T2	Hospital Beds for Adults
TS EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

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Authorization Person : Bülent ARAS
Position : Yönetim Kurulu Üyesi
Document Issuing Date : 06.10.2021

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