

تاریخ | Date 09.09.2022
شماره | Number 1000-822
پیوست | Attach

EU DECLARATION OF CONFORMITY

Registered Commercial Title and Address of the Manufacturer:

SINA HAMD ARIA, SHAHID SALIMI INDUSTRIAL TOWN, AZARSHAHR Rd, TABRIZ, IRAN

Deputy CEO: MAHDI AHMAD PUOR

Actor ID/SRN: IR-MF-000025622

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EUROPEAN AUTHORIZED REPRESENTATIVE PROFILE: HAMID DEYLAM SALEHI

Actor ID/SRN: RO-AR-000023569

Risk class of the device according to the rules set forth in the attachment: CLASS 1

We are the manufacturer of the devices listed below and that the devices are compliant with the medical device regulation (EU) 2017/745 (MDR) And meet all relevant requirements within the MDR.

Method of assessment of conformity: Annex IV declaration of conformity (Annex II & Appendix III) Chapter III (classification) of the products medical device regulation, fifth edition – Rule 1, Rule 12 / CLASS: 1. All non – invasive devices are classified class 1.

Common specifications: EN ISO 13485:2016 – EN ISO 9001:2015

Notified body information:

ISO 9001:2015 & EN ISO 13485:2016

IMQ -Via Quintiliano 43-20138 Milano-Italy

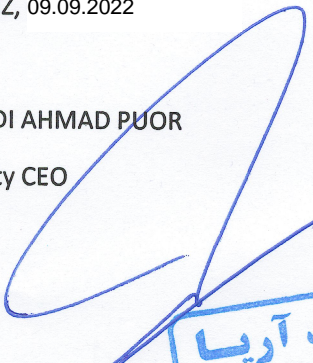
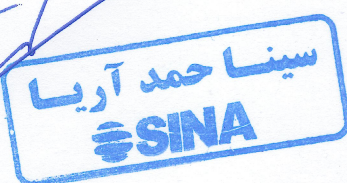
THIS DECLARATION OF CONFORMITY IS CREATED SOLELY UNDER THE MANUFACTURERS RESPONSIBILITY.

PLACE AND DATE OF ISSUING THE DECLARATION,

TABRIZ, 09.09.2022

MAHDI AHMAD PUOR

Deputy CEO

Item	Product Name شماره پست	Date تاریخ	Number Attatch	Product code	Brand	Risk Class	Basic UDI-DI Number	UDI-DI Number
1	M24.2			9018000013	EXAMINATION BED	Class 1	5944759076EXAMBED4V	5944759076075
2	ATRIA MT			9001010318	MECHANICAL BED	Class 1	5944759076MECANICALBEDKM	5944759076273
3	A311PO21			9001010416	MECHANICAL BED	Class 1	5944759076MECHANICBEDLE	5944759076280
4	A311PO21.4			9001010472	MECHANICAL BED	Class 1	5944759076MECHANICALBEMN	5944759076297
5	A311PO26			9001020129	MECHANICAL BED	Class 1	5944759076MECHANICALBEDSD	5944759076303
6	A401P.1			9012010025	MECHANICAL BED	Class 1	5944759076MECHANIBEDST	5944759076181
7	S1200			2600000008	WARD STRETCHER	Class 1	5944759076WARDSTRETCHRSBE	5944759076211
8	S1400			9005010188	WARDSTRETCHER	Class 1	5944759076WARDSTRETCHERA5	5944759076259
9	S4100.1			9005010001	WARD STRETCHER	Class 1	5944759076WARDSTRETCHRW	5944759076204
10	S4100.2			9005010100	EMERGENCY STRETCHER	Class 1	5944759076EMRGENCYSTREFB	5944759076051
11	S4100.3			9005010199	HYDRAULIC STRETCHER	Class 1	5944759076HYDRA_STRCHEREX	5944759076044
12	STRA4143.1			9005010078	EMERGENCY STRTECHER	Class 1	5944759076EMGNSTRETCHERX9	5944759076150
13	STRA4243			9005010133	EMERGENCY STRETCHER	Class 1	5944759076EMGSTRETCHERSWK	5944759076099
14	STRA 5144			9005010166	EMERGENCY STRETCHER	Class 1	5944759076EMGSTRETCHERJB	5944759076235

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15	STRA 6144	9005010200	EMERGENCY STRETCHER	Class 1	5944759076EMGYSTRETCHER9B	5944759076310
16	R1111FS	9007010106	PSYCHOLOGYCAL BED	Class 1	5944759076PSYCHOLOGYBEDGD	5944759076327
17	B0050	9008010000	PEDIATRIC BED	Class 1	5944759076PEDIATRICBED2U	5944759076228
18	B0060.2	9008010132	CHILDREN BED	Class 1	5944759076CHLDBDB0060.2MW	5944759076372
19	BDC2111211	9023000008	BLOOD DONOR CHAIR	Class 1	5944759076BLDONORCHAIR2X	5944759076198
20	ASA R6120	9006010059	RECLINERS BED	Class 1	5944759076RECLINERSBED9A	5944759076242
21	CASTIA DT3101POCE1.2	9003000051	DELIVERY BED	Class 1	5944759076DELIVERYBED29	5944759076143
22	SCALA T2101POOO	9009020442	ELECTRICAL BED	Class 1	5944759076ELECTRICBEDV7	5944759076112
23	SCALA L3000POO	9009020387	ELECTRICALBED	Class 1	5944759076ELECBEDEATRIAFZ	5944759076006
24	SCALA T4001PROO	9009020574	ELECTRICALBED	Class 1	5944759076ELECTRICYBED2T	5944759076358
25	SCALA T4301 PRO	9009020431	ELECTRICYBED	Class 1	5944759076ELECTRICABEDVG	5944759076341
26	SCALAT4401PROO.2	9009020541	ELECTRICALBED	Class 1	5944759076ELECTRICLBEDXV	5944759076334
27	H3140	9010000020	DIYALISISBED	Class 1	5944759076DIYALISISBEDDKL	5944759076365
28	A311E	9001020107	ELECTICALBED	Class 1	5944759076ELECTICALBEDPY	5944759076174

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29	OBT02	9002010376	OVER BED TABLE	Class 1	5944759076OVERBEDTABLC6	5944759076136
30	OBT05	9002020518	FOOD TABLE	Class 1	5944759076FOODTABLEAT	5944759076068
31	OBT08	9002010981	OVERBEDTABLE	Class 1	5944759076OVERBEDTABLEGJ	5944759076020
32	M52.5	9002020551	BED SIDE CABINET	Class 1	5944759076BEDSIDCABINEEX	5944759076129
33	M52.7	9002020584	BEDSIDE CABINET	Class 1	5944759076BEDSIDE CABINELQ	5944759076013
34	M52.8	9002020595	BEDSIDE CABINET	Class 1	5944759076BEDSIDE CABINTMN	5944759076013
35	ACIP02	9002010200	IV POLE	Class 1	5944759076IVPOLEXM	5944759076082
36	M20000010.90 10	9002010628	MATTRESS	Class 1	5944759076MATTRESSV2	5944759076105
37	PA11111	9022000005	SCREEN	Class 1	5944759076SCREENTX	5944759076167



سینا حمد آریا
SINA