

DECLARATION OF CONFORMITY

We are solely responsible for declaring that the Medical Devices mentioned in this statement are of Low-Risk Class (Class I) and comply with the requirements of the European Regulation 2017/745 and where appropriate, the standards and legislation referred to.

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COMPETENT AUTHORITY:	National Organization for Medicines
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LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
WHEELCHAIR GEMINI (SEAT 41CM, 24")	0811306	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI (SEAT 43CM, 24")	0811301	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI (SEAT 46CM, 24")	0811300	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR "ADAPT" 46CM 24" (110KG)	0811308	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR HEAVY DUTY	0808527	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM IV. QR "LION" 41CM	0810804	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM IV. QR "LION" 43CM	0810805	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR FOR CHILDREN "RAINBOW" (SEAT WIDTH 35CM)	0811311	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR FOR CHILDREN CEREBAL PALSY "SAMMY" BLUE (SEAT WIDTH 28-32CM)	0811312	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR FOR CHILDREN CEREBAL PALSY "SAMMY" ORANGE (SEAT WIDTH 28-32CM)	0811313	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE (SEAT 43CM, 24")	0811301B	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE (SEAT 46CM, 12")	0811302B	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE (SEAT 43CM, 12")	0811303B	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE BASIC (SEAT 46CM, 24")	0811604	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE (SEAT 46CM, 24")	0811300B	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI BLUE COMMODE (SEAT 43CM, 5")	0811605	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI (SEAT 41CM, 12')	0811307	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI (SEAT 43CM, 12')	0811303	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI (SEAT 46CM, 12')	0811302	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE (SEAT 45, 5" WHEELS)	0810120	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

WHEELCHAIR BASIC I	0808383i	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM IV. QR "LION" 46CM	0810806	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
GOLDEN WHEELCHAIR RED- BLACK (SEAT 46CM)	0808480	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
GOLDEN WHEELCHAIR BLUE- BLACK (SEAT 46CM)	0808481	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR "ELITE"	0806105	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
"BASIC I" WHEELCHAIR	0808383	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
BASIC II WHEELCHAIR (SEAT 41CM)	0808483	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ECONOMY I SOLID	0813016	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM II -FIX- Q.R.-PREMIUM	0810802	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM III -Q.R. "EXCECUTIVE"	0810803	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR ALUMINUM III. QR "EXCECUTIVE" 41CM SEAT	0810807	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
CEREBRAL PALSY WHEELCHAIR (SEAT WIDTH 36CM, HEAD SUPPORT)	0808505	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR RECLINING	0809236	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
RECLINING WHEELCHAIR WITH COMMODE (SEAT 47CM)	0806062	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
TRANSFER ALUMINUM WHEELCHAIR BLUE (SEAT 41)	0808377	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
INDOOR WHEELCHAIR BASIC IV (SEAT 46CM)	0810170	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
INDOOR WHEELCHAIR I (SEAT 46CM)	0806778	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE III	0808367	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE	0223004	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
INDOOR WHEELCHAIR III WITH COMMODE	0807985	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE	0806053	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE	0806777	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

FOLDABLE WHEELCHAIR WITH COMMODE (SEAT 45, 5" WHEELS)	0808396	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE BLUE	0808378	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
CEREBRAL PALSY WHEELCHAIR	0808612	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
RECLINING WHEELCHAIR	0808837	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
RECLINING WHEELCHAIR	0808838	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ALUMINUM COMMODE CHAIR "ASPER" (136KG)	0805454	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
COMMODE CHAIR CYAN (136KG)	0805453	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR BASIC II No41	0804485	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
"GEMINI" SILVER,MAX LOAD:125KG, SEAT:46CM, WHEELS:24"	0811607	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR WITH COMMODE	0811608	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 48cm 24"QR	0811700	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 46cm 24"QR	0811701	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 43cm 24"QR	0811702	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 40cm 24"QR	0811703	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 38cm 24"QR	0811704	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WHEELCHAIR GEMINI COMF. 36cm 24"QR	0811705	521300690wheelchairs1F3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

CONFORMITY ASSESSMENT PROCEDURE

According to Annexes II & III of Regulation (EU) 2017/745

APPLIED STANDARDS & LEGAL REQUIREMENTS

ISO 13485:2016, ISO 9001:2015, EN ISO 14971: 2019, EN ISO 15223-1:2021, EN ISO 20417:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, EN 62366-1:2015, EN 12183:2022, ISO 7176-8:2014, ISO 10542-1:2012, ISO 7176-1:2014, ISO 7176-3:2012, ISO 7176-5:2008, (EU) 2017/745



FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	24/11/2022
SIGN:	

