

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
SHOWER CHAIR WITH BACKREST	0806064i	521300690chairs124V	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
SHOWER CHAIR W/O BACKREST	0806505i	521300690chairs124V	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
HEAVY DUTY SHOWER CHAIR WITH BACKREST (MAX LOAD 225KG)	0808523	521300690chairs124V	CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
BATHTUB TRANSFER CHAIR	0810067	521300690chairs124V	PORTABLE, FIXED OR FOLDING TOILET CHAIRS WHICH THE PATIENT CAN MAKE HIS PHYSICAL NEED	1
ALUMINIUM ROUND BATH STOOL	0807545	521300690chairs124V	CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
SHOWER CHAIR WITH BACKREST	0806064	521300690chairs124V	CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
SHOWER CHAIR WITHOUT BACKREST	0806505	521300690chairs124V	CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
SHOWER CHAIR WITHOUT BACKREST	0808876	521300690chairs124V	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
SQUARE SHOWER STOOL ADJ. "PRIME"	0805514	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
RECTANGULAR SHOWER SEAT "PRIME"	0805515	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
RECTANGULAR SHOWER SEAT WITH BACKREST "PRIME"	0805516	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1

BATHTUB SEAT "PRIME"	0805517	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
BATHTUB SEAT WITH BACKREST "PRIME"	0805518	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	1
WALL MOUNTED SHOWER SEAT "PRIME"	0805519	521300690chairs124V	PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM	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 12520:2016, ISO 17966:2016, (EU) 2017/745



FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	23/11/2022
SIGN:	

