

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
BACKREST	0808341	521300690rsdtoilseats6LE	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
BACKREST (ANGLE) (56CM X 59CM)	0806066	521300690rsdtoilseats6LE	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
RAISED TOILET SEAT 10CM WITH SIDE CLAMPS (10CM)	0808231	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT 15CM WITH SIDE CLAMPS (15CM)	0808345	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT 10CM WITH LID	0808183	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT 15CM WITH LID	0808184	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1

RAISED TOILET SEAT 10CM WITH FRONT LOCK & ARMREST	0806702	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT 10CM WITH FRONT LOCK	0806070	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH LOCKING SYSTEM 10CM/4"	0805510	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH LOCKING SYSTEM 15CM/6"	0805511	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH LOCKING SYSTEM 10CM/4" WITH LID	0805512	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH LOCKING SYSTEM 15CM/6" WITH LID	0805513	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH FRONTAL LOCKING SCREW 12,5CM/5" W/ FIXED ARMRESTS	0805526	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	1
RAISED TOILET SEAT WITH FRONTAL LOCKING SCREW 12,5CM/5" W/ FOLDING ARMRESTS	0805527	521300690rsdtoilseats6LE	ACCESSORIES THAT ARE PLACED IN THE TOILET BASIN	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, ISO 20417:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, (EU) 2017/745

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FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	22/11/2022
SIGN:	

