

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
CONTACT DETAILS:	Address: Mesogeion 284, PS 15562, Cholargos Phone : 2132040000 Website: https://www.eof.gr/

LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
BATHTUB SEAT (FIXED)	0806065	521300690bathtubs22RR	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ADJUSTABLE BATHTUB BENCH	0808366	521300690bathtubs22RR	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, (EU) 2017/745



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

