

### **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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<b>COMPETENT AUTHORITY:</b>	<b>National Organization for Medicines</b>
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LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
MATTRESS COVER WATERPROOF, 200X90X10CM BLUE COLOR	0806634	521300690covers23FW	SUITABLE FOR HOSPITAL OR HOME USE	1
WATERPROOF ARM COVER (ADULT 22INCHES/56 CM)	0808511	521300690covers23FW	INTENDED TO BE USED AS A WATERPROOF CAST OR BANDAGE PROTECTOR WHEN SHOWERING OR BATHING.	1
WATERPROOF ARM COVER (CHILD 18INCHES/45 CM)	0808512	521300690covers23FW	INTENDED TO BE USED AS A WATERPROOF CAST OR BANDAGE PROTECTOR WHEN SHOWERING OR BATHING.	1
WATERPROOF LEG COVER ( ADULT 23INCH/58 CM)	0808513	521300690covers23FW	INTENDED TO BE USED AS A WATERPROOF CAST OR BANDAGE PROTECTOR WHEN SHOWERING OR BATHING.	1
WATERPROOF LEG COVER (CHILD 18INCH/45 CM)	0808514	521300690covers23FW	INTENDED TO BE USED AS A WATERPROOF CAST OR BANDAGE PROTECTOR WHEN SHOWERING OR BATHING.	1

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

APPLIED STANDARDS & LEGAL REQUIREMENTS
ISO 13485:2016, ISO 9001:2015, (EU) 2017/745



FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	10/10/2024
SIGN:	

