

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
ELECTRIC BED, 3-FUNCTIONS (WITH RAILS & WHEELS)	0808470	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	13
SEMI-ELECTRIC BED 3-FUNCTIONS (WITH RAILS & WHEELS)	0808471	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	13
ECO. HOMECARE BED "LIBRA" WITH WOODEN COVERS	0803151	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	1
ECO. HOMECARE BED "VIRGO" W/O WOODEN COVERS	0803152	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	1
HOSPITAL BED 3 FUNCTION ELECTRIC	0805425	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	1
HOSPITAL TYPE BED 3 FUNCTION ELECTRIC	0805427	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	1
HOSPITAL BED ELECTRIC 3-FUNCTIONS	0806054	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	1
ELECTRIC BED, 5-FUNCTIONS DARK BROWN	0806449	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	13
ELECTRIC BED, 5-FUNCTIONS WHITE	0806450	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	13
ELECTRIC BED 1-FUNCTION	0810059	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWER SUPPLY, BED CARE OF HOSPITALS, FOR HOSPITALS & HOSPITALS, HOMES	13
EXAMINATION ELECTRICAL BED "DELUXE"	0806421	521300690electricbeds4B7	EXAMINATION BED OF MEDICAL PATIENTS, CLINIC OR HOSPITAL	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 1041:2008, ISO 10993-1:2018, ISO 10993-5:2009, EN ISO 10993-10:2013, EN 60601-1-2:2014, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 60601-2-52:2010+A1:2015, EN 60601-1:2006/A1:2013, EN 62366-1:2015, (EU) 2017/745



FOR APPROVAL

NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	24/05/2021
SIGN:	

