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.

MANUFACTURER:	**MOBIAK S.A**
SRN:	**GR-MF-000016256**
SEAT ADDRESS:	**KATHIANA AKROTIRIOU-CHANIA-CRETE-GREECE**
E-MAIL:	**mobiakcarequality@mobiak.com**
TELEPHONE:	**+30 2821063222**
WEB SITE:	**www.mobiakcare.com**

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**
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
HOMECARE ELECTRIC BED "DIAS" FOR HOSPITAL USE	0805600	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	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

HOMECARE ELECTRIC PEDIATRIC BED "KIDS" FOR HOSPITAL USE	0805624	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13

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

CE

FOR APPROVAL	
NAME:	**SVOURAKI MARIA**
POSITION:	**CEO**
PLACE:	**CHANIA**
DATE:	**13/10/2022**
SIGN:	

INDUSTRIAL AND MEDICAL GASES OF CRETE
NOBIAK