

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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| MANUFACTURER: | MOBIAK S.A |
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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 |
|---|-------------|--------------------------|--|-------------|
| ELECTRIC BED, 3-FUNCTIONS (WITH RAILS & WHEELS) | 0808470 | 521300690electricbeds4B7 | BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 13 |
| SEMI-ELECTRIC BED 3-FUNCTIONS (WITH RAILS & WHEELS) | 0808471 | 521300690electricbeds4B7 | BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 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, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 1 |
| ELECTRIC BED, 5-FUNCTIONS DARK BROWN | 0806449 | 521300690electricbeds4B7 | BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 13 |
| ELECTRIC BED, 5-FUNCTIONS WHITE | 0806450 | 521300690electricbeds4B7 | BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 13 |
| ELECTRIC BED 1-FUNCTION | 0810059 | 521300690electricbeds4B7 | BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE | 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, ISO 20417:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, 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

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| NAME: | SVOURAKI MARIA |
| POSITION: | CEO |
| PLACE: | CHANIA |
| DATE: | 21/11/2022 |
| SIGN: | |

