

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 |
|---|-------------|---------------------------|-----------------------------------|-------------|
| 4-OUTLET PUMP ANALOG FOR PRESSURE THERAPY | 0806210 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-OUTLET PUMP DIGITAL FOR PRESSURE THERAPY | 0806211 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-OUTLET PUMP DIGITAL WITH BATTERY FOR PRESSURE THERAPY | 0806212 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION LEG CUFF MEDIUM 91X61 CM | 0806213 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION LEG CUFF OVERLAPPING 110X70 CM | 0806214 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION ARM CUFF MEDIUM 87X51 CM | 0806216 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION ARM CUFF OVERLAPPING 90X60 CM | 0806217 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION WAIST CUFF MEDIUM 120X37 CM | 0806218 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION WAIST CUFF LARGE 130X37 CM | 0806219 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 1 |
| 4-SECTION LEG CUFF XLARGE OVERLAPPING | 0806225 | 521300690presstherapy282A | SUITABLE FOR HOSPITAL OR HOME USE | 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 60601-1-11:2015, EN ISO 15223-1:2021, (EU) 2017/745



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

