

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:	+302821063222
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
ANTI-DECUBITUS BUBBLE MATTRESS FOR MASSAGE WITH AIR PUMP	0223005	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	13
AIR-CELL SPARE MATTRESS	0807750	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP FOR AIR BUBBLE MATTRESS	0223021	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
SPARE STRIP MATTRESS	0808279	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS STRIPE MATTRESS WITH VENTILATION HOLES FOR MASSAGE WITH AIR PUMP	0810160	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	13
SPARE STRIP MATTRESS WITH HOLES	0810561	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS BUBBLE MATTRESS WITH AIR PUMP MINOA	0806270	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS BUBBLE MATTRES MINOA	0806271	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS BUBBLE MATTRESS WITH AIR PUMP PREMIUM OCEAN	0806276	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS BUBBLE MATTRES OCEAN	0806277	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS STRIPE MATTRESS WITH VENTILATION, CPR & AIR PUMP	0806285	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
	0806286	521300690matrandpumps13BL		1

ANTI-DECUBITUS STRIPE MATTRESS WITH VENTILATION, CPR			SUITABLE FOR HOSPITAL OR HOME USE	
ANTI-DECUBITUS HOSPITAL STRIPE MATTRESS 5"+3" FOAM MATTRESS & AIR PUMP	0806288	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS HOSPITAL STRIPE MATTRESS 5"+3" FOAM MATTRESS	0806289	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS HOSPITAL ICU STRIPE MATTRESS 8" & AIR PUMP	0806293	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS HOSPITAL ICU STRIPE MATTRESS 8"	0806294	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP FOR ANTI-DECUBITUS BUBBLE MATTRESS MINOA	0806272	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP " PREMIUM" FOR ANTI-DECUBITUS MATTRESS	0806278	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP FOR ANTI-DECUBITUS HOSPITAL STRIPE MATTRESS 5"+3" FOAM MATTRESS	0806290	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP FOR ANTI-DECUBITUS HOSPITAL ICU STRIPE MATTRESS 8"	0806295	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
PUMP FOR AIR-STRIPPE MATTRESS	0808578	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS STRIPE MATTRESS FOR MASSAGE WITH AIR PUMP (150KG)	0806591	521300690matrandpumps13BL	SUITABLE FOR HOSPITAL OR HOME USE	1

CONFORMITY ASSESSMENT PROCEDURE

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

APPLIED STANDARDS & LEGAL REQUIREMENTSISO 13485:2016, ISO 9001:2015, EN 60601-1-2:2015, EN 60601-1:2005/AMD1:2012, ISO 10993-1:2018,
ISO 10993-10:2021, ISO 10993-5:2009, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 60601-1:2006/A12:2014,
(EU) 2017/745

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

