

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
SINGLE MONKEY POLE WITH HANDLE	0805423	521300690bedaccsries25HX	SUITABLE FOR HOSPITAL OR HOME USE	1
CASTORS WITH BRAKE FOR MANUAL BED	0805422	521300690bedaccsries25HX	SUITABLE FOR HOSPITAL OR HOME USE	1
LIFTING POLE (FOR BEDS 0808470 & 0808471)	0809251	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
MONKEY POLE WITH BASE	0808195	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
I.V STAND WITH 4 HANGERS & PLASTIC BASE	0806392	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
I.V STAND WITH 2 HANGERS & ALUMINUM BASE	0808235	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
WHEELS WITH BRAKES (FOR BEDS 0810068-71, 058-059)	0810074	521300690bedaccsries25HX	ESSENTIAL ACCESSORY TO USE THE MANUAL DIVIDED AND MULTIPLE BED	1
I.V STAND WITH 4 HANGERS & ALUMINUM BASE	0806377	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
HOSPITAL-GRADE IV STAND WITH TRAY	0805979	521300690bedaccsries25HX	BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT	1
ADJUSTABLE BED HANDLE LADDER TYPE	0803654	521300690bedaccsries25HX	DESIGNED TO FACILITATE THE PATIENT'S CHANGE FROM LYING TO SITTING AND VICE VERSA, WITHOUT THE HELP OF A CAREGIVER.	1
BED RAILS WITH ADJUSTABLE LENGTH	0813171	521300690bedaccsries25HX	DESIGNED TO PREVENT AN INDIVIDUAL FALL FROM ANY BED, FOR HOSPITAL OR HOME CARE.	1
BACKREST LIFT	0806066	521300690bedaccsries25HX	DESIGNED AS A BED AID AND FOR BACK LIFTING OF PEOPLE WHO ARE IN BED FOR A LONG TIME	1

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

APPLIED STANDARDS & LEGAL REQUIREMENTS
ISO 13485:2016, ISO 9001:2015, (EU) 2017/745

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FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	DIRECTOR OF MEDICAL DEPARTMENT
PLACE:	CHANIA
DATE:	02/03/2026
SIGN:	

