

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
FOREARM CRUTCH WITH FIXED HANDLE AND TETRAPOD BASE	0810066	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH, BLUE, FIXED HANDLE	0809783	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH, GREEN, FIXED HANDLE	0809782	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH, MAGENTA, FIXED HANDLE	0809781	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
TETRAPOD CANE, STRAIGHT ARM	0806510	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
TETRAPOD STANDARD CANE (SWAN)	0809361	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
TRIPOD CANE, CONICAL BASE (COL: SILVER)	0807662	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH, FIXED HANDLE	0806531	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH, ADJUSTABLE HANDLE, GREY (HEIGHT 74-115CM) PC	0806104	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
UNDERARM CRUTCH SMALL	0809776	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE	1

(93-113CM) (GREY) PAIR			RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	
UNDERARM CRUTCH MEDIUM (113-133CM) (GREY) PAIR	0809777	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
UNDERARM CRUTCH LARGE (133-153CM) (GREY) PAIR	0809778	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
UNDERARM CRUTCH REINFORCED SMALL, GREY, PAIR	0804521	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
UNDERARM CRUTCH REINFORCED MEDIUM, GREY, PAIR	0804522	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
UNDERARM CRUTCH REINFORCED LARGE, GREY, PAIR	0804523	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOREARM CRUTCH, ADJUSTABLE HANDLE, BLACK (HEIGHT 85- 115CM)	0806530	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
TETRAPOD CANE, CONICAL BASE (COL: SILVER)	0806529	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
BARIATRIC TETRAPOD CANE, LARGE BASE (100- 225 KGR)	0809772	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
BARIATRIC TETRAPOD CANE. SMALL BASE (100- 225 KGR)	0809771	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1

BARIATRIC UNDERARM CRUTCHES MEDIUM (HEIGHT 157,5CM - 178CM)	0809767	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
BARIATRIC UNDERARM CRUTCHES LARGE (HEIGHT 178CM - 198CM)	0809768	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
BARIATRIC CANE (225KG)	0809377	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE ALUMINIUM STICK, BLACK-PLASTIC HANDLE	0809256	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE ALUMINIUM STICK, BROWN-PLASTIC HANDLE	0806523	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ADJUSTABLE ALUMINIUM STICK, BLACK-PLASTIC HANDLE	0809246	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ADJUSTABLE ALUMINIUM STICK, BROWN-PLASTIC HANDLE	0806520	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE ALUMINIUM STICK, WOOD PATTERN - WITH WOOD HANDLE	0809257	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE ALUMINIUM STICK, SQUARES PATTERN WITH WOOD HANDLE	0809258	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE ALUMINIUM STICK, RED FLOWER- WITH WOOD HANDLE	0809259	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

FOLDABLE ALUMINIUM STICK, BLUE FLOWER- WITH WOOD HANDLE	0809260	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE ALUMINUM STICK, WITH "TIGER FOLDING " PATTERN, WITH WOOD HANDLE	0809261	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ADJUSTABLE STICK WITH SELF-STAND FERRULE & LIGHT	0810207	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH BLUE, REINFORCED	0808466	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH BLACK, REINFORCED	0808467	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOREARM CRUTCH GREY, REINFORCED	0808468	521300690WALKINGAIDS10N3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
BARIATRIC UNDERARM CRUTCHES SMAL	0810799	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
QUADE CANE	0806529i	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
TRIPOD CANE	0807662i	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
TETRAPOD CANE, LARGE BASE (SWAN)	0809667	521300690WALKINGAIDS10N3	USE BY PEOPLE WITH MOBILITY PROBLEMS	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 ISO 14971: 2019, EN ISO 15223-1: 2021, EN ISO 20417:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 24415-1:2009, ISO 24415-2:2011, ISO 11334-1:2007, (EU) 2017/745

CE

FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	23/12/2022
SIGN:	

