

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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COMPETENT AUTHORITY:	National Organization for Medicines
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LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
ROLLATOR WALKER BLUE	0810616	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
RECIPROCATING WALKER	0809396i	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE WALKER WITH 2 LEVEL HANDLES	0807998i	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
HEAVY DUTY FOLDABLE WALKER (58,5CM)	0811606	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR 3 WHEEL "DELTA" GREY	0811310	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER ALUMINUM SILVER WITH CRUTCH HOLDER	0808491	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR, WALKER WITH 3 WHEELS	0808717	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE WALKER	0806508	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
REHABILITATION WALKER	0810007	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE WHEELS WALKER	0806507	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ROLLATOR WALKER RED	0809175	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1

FOLDABLE WALKER WITH 2 LEVEL HANDLES	0807998	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
FOLDABLE WALKER, "STEP BY STEP" MOTION	0809396	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ROLLATOR WALKER 'ACTION BLACK'	0803610	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER 'ACTION WHITE'	0803611	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER ALUM. SILVER 'PLATINUM'	0803160	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE WALKER (110KG)	0809360	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ROLLATOR WITH ANTIBRACHIAL SUPPORT	0807567	521300690walkers11K3	WALKING AIDS FOR THE DISABLED, USED FOR THE RECOVERY OR WALK ASSISTANCE OF THE PATIENT OR DISABLED	1
ROLLATOR WITH ANTIBRACHIAL SUPPORT (136KG)	0805452	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
FOLDABLE INFANT WHEELED WALKER	0808819	521300690walkers11K3	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 1041:2008, ISO 10993-1:2018, ISO 10993-5:2009, EN ISO 10993-10:2013, ISO 11199-2:2005, ISO 11199-3:2005, ISO 11199-1:2021, EN 62366-1:2015, (EU) 2017/745



FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	24/05/2021
SIGN:	

