

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 ALIMINUM 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 (115kg)	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
FOLDABLE WALKER (136kg)	0809786	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
WALKER, FOLDABLE, "STEP BY STEP" MOTION (136 KG)	0809787	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER ALUMIN. "WALKY"	0805492	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER RUBY	0805499	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER INDIGO	0805411	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
HEAVY DUTY FOLDABLE WALKER (225KG)	0812200	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

ROLLATOR WALKER MIGHTY	0812215	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
KNEE WALKER STROLLY	0815019	521300690walkers11K3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
ROLLATOR WALKER 2 IN 1 "FLEXY"	0813100	521300690walkers11K3	IT IS INTENDED TO SUPPORT AND IMPROVE LIMITED WALKING ABILITY.	1
ROLLATOR WALKER WITH TRAY	0813101	521300690walkers11K3	IT IS INTENDED TO SUPPORT AND IMPROVE LIMITED WALKING ABILITY.	1
ROLLATOR WALKER 2 IN 1 "CHERRY"	0813102	521300690walkers11K3	IT IS INTENDED TO SUPPORT AND IMPROVE LIMITED WALKING ABILITY.	1
2 WHEELS ROLLATOR	0805408	521300690walkers11K3	WALKERS CAN BE USED BY PEOPLE WITH LIMITED MOBILITY TO MOVE AROUND INSIDE AND OUTSIDE THE HOME.	1
ROLLATOR WALKER WITH ARMRESTS "I-STAND"	0813169	521300690walkers11K3	THEY CAN BE USED BY PEOPLE WITH LIMITED MOBILITY FOR MOVING IN AND OUT OF THE HOME.	1
WALKER WITH 360° SWIVEL CASTORS	0810643	521300690walkers11K3	THEY CAN BE USED BY PEOPLE WITH LIMITED MOBILITY FOR MOVING IN AND OUT OF THE HOME.	1
ELECTRIC ROLLATOR WALKER "HYBRID"	0811951	521300690walkers11K3	IT ALLOWS THE USER TO EITHER USE IT AS A WALKING ASSISTANT BY PUSHING IT, OR TO SIT AND MOVE ELECTRICALLY USING THE JOYSTICK	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 11199-2:2021, ISO 11199-3:2005, ISO 11199-1:2021, EN 62366-1:2015, (EU) 2017/745



FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
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SIGN:	

