

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
POWER WHEELCHAIR, ALUMINUM CONVERT	0810800	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
POWER WHEELCHAIR, ALUMINUM VENERE	0808714	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
POWER WHEELCHAIR RECLINING "COMFORT"	0809242	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
POWER WHEELCHAIR FOLDABLE "VOYAGER" (120KG)	0811316	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
POWER WHEELCHAIR STEEL "HERMES II" (120KG)	0811315	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
Power wheelchair Aluminum "TITAN" RECLINER (130KG)	0811317	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
POWER WHEELCHAIR FOLDABLE "ODYSSEUS"	0805700	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
SCOOTER-TYPE FOLDABLE APOLLO	0811800	521300690scooters319G	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
SCOOTER-TYPE "ARES"	0811820	521300690scooters319G	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
ELECTRIC WHEELCHAIR "ROBODRIVE"	0805720	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
ELECTRIC WHEELCHAIR "TECHRIDE"	0805721	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
ELECTRIC WHEELCHAIR "TURBOTECH"	0805722	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
POWER WHEELCHAIR IKARUS	0805912	521300690pwwheelchairs2T3	USE BY PEOPLE WITH MOBILITY PROBLEMS	1

CONFORMITY ASSESSMENT PROCEDURE
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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, EN 62366-1:2015, IEC 60601-1:2005+AMD1:2012,EN 60601-1-2:2014, EN 62304:2006+A1:2015, EN 60601-1-6:2013, EN 12183:2022, (EU) 2017/745



FOR APPROVAL

NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	20/03/2024
SIGN:	

