

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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LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
ELECTRIC FOLDABLE PATIENT LIFT "ACHILLEAS" WITHOUT SLING	0803150	521300690patientlrs14PP	SUITABLE FOR HOSPITAL OR HOME USE	13
PATIENT LIFT MBC PEGASUS (135KGR)	0804900	521300690patientlrs14PP	LIFTING AND TRANSPORTATION OF PATIENTS, FOR PEOPLE WITH QUADRIPLÉGIA , TO PEOPLE WITH PARALLELISM WHICH IS BEDRIDDEN AND LIFTING PEOPLE WITH LIMITED MOBILITY	13
PATIENT LIFT MBC ATLAS (150KG)	0808038	521300690patientlrs14PP	LIFTING AND TRANSPORTATION OF PATIENTS, FOR PEOPLE WITH QUADRIPLÉGIA , TO PEOPLE WITH PARALLELISM WHICH IS BEDRIDDEN AND LIFTING PEOPLE WITH LIMITED MOBILITY	13
PATIENT LIFT MBC TALOS (180KGR)	0804902	521300690patientlrs14PP	LIFTING AND TRANSPORTATION OF PATIENTS, FOR PEOPLE WITH QUADRIPLÉGIA , TO PEOPLE WITH PARALLELISM WHICH IS BEDRIDDEN AND LIFTING PEOPLE WITH LIMITED MOBILITY	13
PATIENT LIFT MBK ELECTRIC ATLAS II (150kgr)	0804935	521300690patientlrs14PP	USED BY PEOPLE WITH MOBILITY PROBLEMS	13
PATIENT LIFT MBK ELECTRIC TALOS II (200kgr)	0804936	521300690patientlrs14PP	USED BY PEOPLE WITH MOBILITY PROBLEMS	13
STAND UP MBK (200 kg)	0804937	521300690patientlrs14PP	USED BY PEOPLE WITH MOBILITY PROBLEMS	13

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, EN 62366-1:2015, EN 60601-1-2:2015, EN 60601-1-2:2014, ISO 10535:2006, EN 60601-2-52:2009, EN 60068-2-1-31:2008, EN 61000-6-3:2001/A11:2004, EN 61000-6-1:2019, (EU) 2017/745

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

