

## 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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<b>COMPETENT AUTHORITY:</b>	<b>National Organization for Medicines</b>
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LIST OF PRODUCTS COVERED BY THIS DECLARATION				
PRODUCT	CODE	BASIC UDI-DI	INTENDED USE	RULE
LIFT CHAIR WITH WHEELS "ESTIA"	0811900	521300690liftchairs328Y	USE BY PEOPLE WITH MOBILITY PROBLEMS	1
LIFT CHAIR WITH WHEELS "ESTIA II"	0811950	521300690liftchairs328Y	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, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 17966:2016, (EU) 2017/745



FOR APPROVAL	
<b>NAME:</b>	<b>SVOURAKI MARIA</b>
<b>POSITION:</b>	<b>CEO</b>
<b>PLACE:</b>	<b>CHANIA</b>
<b>DATE:</b>	<b>12/05/2023</b>
<b>SIGN:</b>	

