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**
PEDAL EXERCISER FIXED	0803155	521300690bikes9UW	PRODUCTS FOR PHYSICS, PHYSICAL THERAPY AND REHABILITATION OF PATIENTS	1
PEDAL EXERCISER DIGITAL-FOLDABLE	0803156	521300690bikes9UW	PRODUCTS FOR PHYSICS, PHYSICAL THERAPY AND REHABILITATION OF PATIENTS	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, EN ISO 21856:2022, EN 62366-1:2015, (EU) 2017/745

CE

FOR APPROVAL	
NAME:	SVOURAKI MARIA
POSITION:	CEO
PLACE:	CHANIA
DATE:	22/11/2022
SIGN: