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**
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

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 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

CE

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

INDUSTRIAL AND MEDICAL GASES OF CRETE
MOBIAK