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**
UNIVERSAL SLING HS/FULL SLING (STD M)	0803121	521300690slings16KB	SUITABLE FOR HOSPITAL OR HOME USE	1
TOILET SLING / DRESS SLING (STD L)	0803122	521300690slings16KB	SUITABLE FOR HOSPITAL OR HOME USE	1
COMFORT SLING WITH HEAD SUPPORT (MESH L)	0803123	521300690slings16KB	SUITABLE FOR HOSPITAL OR HOME USE	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 21856:2022, ISO 10535:2021, ISO 10993-10:2021, ISO 3759:2011, (EU) 2017/745,

CE

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