

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
AIR & GEL CUSHION COZY 41X41X5	0810010	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
GEL CUSHION GEL- TECH I 40X40X1,6CM	0810013	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
GEL CUSHION GEL- TECH II 46X40X1,6CM	0810014	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
GEL CUSHION GEL- TECH 3D I 42X40X2CM	0810011	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
GEL CUSHION GEL- TECH 3D II 46X42X2CM	0810012	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
AIR CELL CUSHION PVC ERGO-LITE 46X40X6/10CM	0810015	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
AIR CELL CUSHION PVC COMFY I 40X40X8CM	0810016	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
AIR CELL CUSHION PVC COMFY II 46X40X8CM	0810017	521300690cushions8R3	PILLOWS & INFLATABLE COLLECTIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DEPRESSIONS	1
ANTI-DECUBITUS STRIPE CUSHION FOR WHEELCHAIRS WITH AIR PUMP	0806296	521300690cushions8R3	SUITABLE FOR HOSPITAL OR HOME USE	1
ANTI-DECUBITUS STRIPE CUSHION FOR WHEELCHAIRS WITH BATTERY AIR PUMP	0806246	521300690cushions8R3	SUITABLE FOR HOSPITAL OR HOME USE	1

AIR CELL CUSHION 35x41x5CM	0810230	521300690cushions8R3	CUSHIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DISABILITIES	1
AIR CELL CUSHION 41x41x5CM	0810231	521300690cushions8R3	CUSHIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DISABILITIES	1
AIR CELL CUSHION 47x41x5CM	0810232	521300690cushions8R3	CUSHIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DISABILITIES	1
AIR CELL CUSHION 47x47x5CM	0810233	521300690cushions8R3	CUSHIONS PLACED ON DIFFERENT PARTS OF THE BODY FOR THE PREVENTION AND COMPLEMENTARY TREATMENT OF DISABILITIES	1
CUSHION "SILICONE I" (50x45x5.5)	0803124	521300690cushions8R3	CUSHIONS DESIGNED TO OFFER HIGH COMFORT TO USERS SITTING FOR LONG PERIODS IN CHAIRS AND WHEELCHAIRS	1
CUSHION "SILICONE II" (45x40x5.5)	0803125	521300690cushions8R3	CUSHIONS DESIGNED TO OFFER HIGH COMFORT TO USERS SITTING FOR LONG PERIODS IN CHAIRS AND WHEELCHAIRS	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 20417:2021
EN ISO 15223-1:2021, (EU) 2017/745



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

