

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
ELECTRIC BED, 3-FUNCTIONS (WITH RAILS & WHEELS)	0808470	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13
SEMI-ELECTRIC BED 3-FUNCTIONS (WITH RAILS & WHEELS)	0808471	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13
HOMECARE ELECTRIC BED "DIAS" FOR HOSPITAL USE	0805600	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
ECO. HOMECARE BED "LIBRA" WITH WOODEN COVERS	0803151	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
ECO. HOMECARE BED "VIRGO" W/O WOODEN COVERS	0803152	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
HOSPITAL BED 3 FUNCTION ELECTRIC	0805425	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
HOSPITAL TYPE BED 3 FUNCTION ELECTRIC	0805427	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
HOSPITAL BED ELECTRIC 3-FUNCTIONS	0806054	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13
ELECTRIC BED, 5-FUNCTIONS DARK BROWN	0806449	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13
ELECTRIC BED, 5-FUNCTIONS WHITE	0806450	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13

ELECTRIC BED 1-FUNCTION	0810059	521300690electricbeds4B7	BED, PERSON WITH SPECIAL NEEDS, POWERED BY ELECTRICAL CABLE, BED HOSPITAL TYPE PATIENT CARE, FOR HOSPITALS, CLINICS & HOME USE	13
EXAMINATION ELECTRICAL BED "DELUXE"	0806421	521300690electricbeds4B7	EXAMINATION BED OF MEDICAL PATIENTS, CLINIC OR HOSPITAL	13
HOMECARE ELECTRIC PEDIATRIC BED "KIDS" FOR HOSPITAL USE	0805624	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
HOSPITAL BED	0805905	521300690electricbeds4B7	SUITABLE FOR HOSPITAL OR HOME USE	13
HOSPITAL BED "PRO"	0805940	521300690electricbeds4B7	USE BY PEOPLE WITH MOBILITY PROBLEMS	13
ELECTRIC HOMECARE BED "VIRGO II"	0811240	521300690electricbeds4B7	Suitable for hospital use	13
ELECTRIC HOMECARE BED "LIBRA II"	0811241	521300690electricbeds4B7	Suitable for hospital use	13
ELECTRIC HOMECARE BED "VIRGO LOW"	0811242	521300690electricbeds4B7	THEY ARE USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "LIBRA LOW"	0811243	521300690electricbeds4B7	THEY ARE USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "VIRGO II LOW"	0811244	521300690electricbeds4B7	THEY ARE USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "LIBRA II LOW"	0811245	521300690electricbeds4B7	THEY ARE USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC BED "ELYSIUM"	0805711	521300690electricbeds4B7	DESIGNED FOR MEDICAL INSTITUTIONS SUCH AS HOSPITALS AND NURSING HOMES, AS WELL AS FOR ELDERLY PEOPLE WITH DISABILITIES AND PEOPLE	13

			WITH LIMITED MOBILITY IN HOUSEHOLDS	
ELECTRIC HOSPITAL BED "PrimeRest I"	0805712	521300690electricbeds4B7	DESIGNED FOR MEDICAL INSTITUTIONS SUCH AS HOSPITALS AND NURSING HOMES, AS WELL AS FOR ELDERLY PEOPLE WITH DISABILITIES AND PEOPLE WITH LIMITED MOBILITY IN HOUSEHOLDS	13
ELECTRIC HOSPITAL BED "PrimeRest II"	0805713	521300690electricbeds4B7	DESIGNED FOR MEDICAL INSTITUTIONS SUCH AS HOSPITALS AND NURSING HOMES, AS WELL AS FOR ELDERLY PEOPLE WITH DISABILITIES AND PEOPLE WITH LIMITED MOBILITY IN HOUSEHOLDS	13
ELECTRIC HOSPITAL BED "PREMIUM"	0805930	521300690electricbeds4B7	USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "KING"	0811250	521300690electricbeds4B7	USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "WOODY"	0811251	521300690electricbeds4B7	USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13
ELECTRIC HOMECARE BED "SIESTA"	0811252	521300690electricbeds4B7	USED FOR PATIENTS WHO HAVE HEALTH PROBLEMS AND NEED TO REMAIN IN BED	13

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 20417:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, EN 60601-1-2:2014, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 60601-2-52:2010+A1:2015, EN 60601-1:2006/A1:2013, EN 62366-1:2015, (EU) 2017/745



FOR APPROVAL	
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