

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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| COMPETENT AUTHORITY: | National Organization for Medicines |
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LIST OF PRODUCTS COVERED BY THIS DECLARATION

| PRODUCT | CODE | BASIC UDI-DI | INTENDED USE | RULE |
|--|-------------|---------------------|---|-------------|
| SHOWER CHAIR WITH BACKREST | 0806064i | 521300690chairs124V | USE BY PEOPLE WITH MOBILITY PROBLEMS | 1 |
| SHOWER CHAIR W/O BACKREST | 0806505i | 521300690chairs124V | USE BY PEOPLE WITH MOBILITY PROBLEMS | 1 |
| HEAVY DUTY SHOWER CHAIR WITH BACKREST (MAX LOAD 225KG) | 0808523 | 521300690chairs124V | CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| BATHTUB TRANSFER CHAIR | 0810067 | 521300690chairs124V | PORTABLE, FIXED OR FOLDING TOILET CHAIRS WHICH THE PATIENT CAN MAKE HIS PHYSICAL NEED | 1 |
| ALUMINIUM ROUND BATH STOOL | 0807545 | 521300690chairs124V | CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| SHOWER CHAIR WITH BACKREST | 0806064 | 521300690chairs124V | CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| SHOWER CHAIR WITHOUT BACKREST | 0806505 | 521300690chairs124V | CHAIRS, STOOLS & PORTABLES, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| SHOWER CHAIR WITHOUT BACKREST | 0808876 | 521300690chairs124V | BED ACCESSORIES FOR THE SAFETY, COMFORT AND HELP OF THE BED PATIENT | 1 |
| COMMODE CHAIR | 0803390 | 521300690chairs124V | USE BY PEOPLE WITH MOBILITY PROBLEMS | 1 |
| SQUARE SHOWER STOOL ADJ. "PRIME" | 0805514 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| RECTANGULAR SHOWER SEAT "PRIME" | 0805515 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| RECTANGULAR SHOWER SEAT WITH BACKREST "PRIME" | 0805516 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |

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| BATHTUB SEAT "PRIME" | 0805517 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| BATHTUB SEAT WITH BACKREST "PRIME" | 0805518 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| WALL MOUNTED SHOWER SEAT "PRIME" | 0805519 | 521300690chairs124V | PORTABLE CHAIRS, STOOLS & STAIRS, FIXED OR FOLDING TO HELP THE DISABLED IN CLEANING INSIDE THE BATHROOM | 1 |
| COMMODE CHAIR SEAL | 0815017 | 521300690chairs124V | USE BY PEOPLE WITH MOBILITY PROBLEMS | 1 |
| BATH CHAIR "WAVE" S BLUE | 0803848 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR "WAVE" M BLUE | 0803849 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR "WAVE" L BLUE | 0803850 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR | 1 |

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| | | | USE IN A BATHROOM ENVIRONMENT. | |
| BATH CHAIR "WAVE" S PINK | 0803851 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR "WAVE" M PINK | 0803852 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR "WAVE" L PINK | 0803853 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR WITH WHEELED BASE S BLUE | 0803857 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
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| BATH CHAIR WITH WHEELED BASE M BLUE | 0803858 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR WITH WHEELED BASE L BLUE | 0803859 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR WITH WHEELED BASE S PINK | 0803860 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| BATH CHAIR WITH WHEELED BASE M PINK | 0803861 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |

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| BATH CHAIR WITH WHEELED BASE L PINK | 0803862 | 521300690chairs124V | IT IS DESIGNED TO PROVIDE SUPPORT AND SAFETY DURING BATHING FOR PEOPLE WITH DISABILITIES, WHO MAY HAVE DIFFICULTY SITTING UPRIGHT OR MAINTAINING THEIR BALANCE. THIS PRODUCT IS FOR INDOOR USE IN A BATHROOM ENVIRONMENT. | 1 |
| 360° ROTATING SHOWER CHAIR | 0805660 | 521300690chairs124V | PROVIDES SUPPORT TO THE ELDERLY, WHEELCHAIR USERS, PEOPLE WITH REDUCED MOBILITY OF THE LOWER LIMBS, LUMBAR AND HIP, AND TO ALL THOSE WHO HAVE DIFFICULTY MAINTAINING AN UPRIGHT POSITION DURING THE SHOWER OR DAILY PERSONAL HYGIENE. | |
| 360° ROTATING BATHTUB TRANSFER BENCH | 0805661 | 521300690chairs124V | PROVIDES SUPPORT TO THE ELDERLY, WHEELCHAIR USERS, PEOPLE WITH REDUCED MOBILITY IN THEIR LOWER LIMBS, BACK AND HIPS, AND TO ALL THOSE WHO HAVE DIFFICULTY MAINTAINING AN UPRIGHT POSITION DURING THEIR DAILY PERSONAL HYGIENE ROUTINE. | 1 |
| BATHTUB SEAT FIXED WITH BACKREST | 0813108 | 521300690chairs124V | DESIGNED TO ALLOW PEOPLE WITH MOBILE PROBLEMS TO BE ABLE TO TAKE A BATH WHILE SITTING ON IT, REDUCING MUSCLE FATIGUE DUE TO THE STANDING POSITION AS WELL AS THE RISK OF SLIPPING. | 1 |
| BATH CHAIR HEAVY DUTY WITH BACKREST | 0813109 | 521300690chairs124V | DESIGNED TO ENABLE PEOPLE WITH MOBILITY PROBLEMS TO TAKE A BATH WHILE SITTING IN IT, REDUCE MUSCLE FATIGUE DUE TO STANDING AND THE RISK OF SLIPPING. | 1 |

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| BATH CHAIR HEAVY DUTY (WITHOUT BACKREST) | 0813110 | 521300690chairs124V | DESIGNED TO ENABLE PEOPLE WITH MOBILITY PROBLEMS TO TAKE A BATH WHILE SITTING IN IT, REDUCE MUSCLE FATIGUE DUE TO STANDING AND THE RISK OF SLIPPING. | 1 |
| WHEELED LABORATORY STOOL | 0805938 | 521300690chairs124V | DESIGNED FOR USE IN MEDICAL, LABORATORY AND PHARMACEUTICAL AREAS, OFFERING HIGH COMFORT, STABILITY AND COMPLETE ERGONOMICS. | 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, EN 12520:2025 ISO 17966:2016, (EU) 2017/745



| FOR APPROVAL | |
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| NAME: | SVOURAKI MARIA |
| POSITION: | CEO |
| PLACE: | CHANIA |
| DATE: | 04/11/2025 |
| SIGN: | |

