



## DECLARATION OF CONFORMITY

### MORSA MEDIKAL ORTOPEDI ve MAK. SAN. TIC. LTD. STI

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We, the undersigned, hereby declare that the products meet the applicable provisions of the council directive (EU) 2017/745 FOR MEDICAL DEVICES.

PRODUCT : Cervical Orthosis, Headrest Covers, Cervical Collars, Spinal Orthosis, Thoracic Orthosis, Lumbar Cushions and Pillows, Shoulder/Elbow/Wrist/Hand Orthosis, Hand/Finger Splints, Suspension Arm Slings, Clavicle Bandages, Corsets, Hip/Knee/Ankle/Foot Orthosis, Knee Braces, Hip/Leg Supports, Hernia Supports, Compression Sock/Stocking, Lymphedema Sleeves, Orthotic Insoles, Silicone Foot / Finger Supports and Protectors, Elastic Bandage, Breast Prosthesis and Brassieres, Wheel Chairs, Walking Frames, Crutches and Supports.(Product List Attached Basic UDI-DI)

CLASSIFICATION : CLASS 1 . RULE 1

ACCORDING TO ANNEX VIII OF THE EU MDR 2017/745

LIST OF HARMONIZED STANDARDS THAT HAVE BEEN USED FOR CONFORMITY ASSESSMENT:

EN ISO 15223-1 EN 1041+A1 EN ISO 14971 EN ISO 13485 EN ISO 9001

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SIGNATURE

Mehmet GÜNALTI  
General Manager

