EC-DECLARATION of CONFORMITY

MANUFACTURER: MiaMed Medikal Teks.Inş.Tur.Gıd.Tic.VE San.LTD
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DESCRIPTION AND FUNCTIONS: MIA PATIENT TRANSPORT WHEEL CHAIR
PRODUCT NAME:MIA G-140
TYPE DESIGNATION:WHEEL CHAIR G-140
PRODUCT CODE: MIA PATIENT TRANSPORT WHEEL CHAIR – MIA G-140
BRAND: MIA MEDICAL
CLASSIFICATION: Class I, Rule 1 according to MDR Regulation (EU) 2017/745
DATE OF VALID: 01.06.2023
ENVIRONMENT of THE INTENDED USE IN: Hospitals, Health Care Facilities
COUNCIL DIRECTIVE: Conformity was assessed by the procedure stated Regulation (EU) 2017/745 Of The European Parliament And Of The Council, Annex IV(Annex II & III).
DATE OF SIGNATURE: 03.01.2021
USED HARMONISED STANDARDS:
TS EN 15223-1:2016–Medical Devices- Symbols to be used with Medical Device Labels, Labelling and Information to Supplied, Part 1: General Requirements
TS EN 60601-1:2006/2009/A1:2013 – Medical Electrical Equipment / Part 1: Medical Products General Requirements for Basic Safety and Essential Performance
TS EN 60601-1-2-2007 EN60601-1-6-2010 IEC 60601-2-38 EN60601-2-52:1-2010
TS EN 55014-1:2017 – Electromagnetic Compatibility (EMC) – Part 3-2: Limits for Harmonic Current Emissions (equipment input current ≤16A per Phase
TS EN 62353:2015 - Medical Electrical Equipment - Recurrent Test and Test after Repair of Medical Electrical Equipment

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We hereby declare that the equipment specified above conforms to the applicable sections of the Council Regulation concerning medical devices (EU) 2017/745. Any modifications made to this product without our express permission and approval shall render this declaration null and void.The Products described above where subject to initial type experiments by Manufacturer and factory manufacture control was carried out by regular tests.

Quality Management System is certified according to Our Company Manufactures the products stated above it accordance with the requirements of the current EN980-1996/A1 (Graphs and Symbols' used on labels),EN1401(Informatıon provided with the Product by Manufacturer),ISO13485/2016 Medical Devices Quality Management System.

DATE: 02.10.2021
SIGNED BY: ALİ CAN İYİGUVEN
General Manager;

Digitally signed by Chirtoacă Iurie
Date: 2022.08.01 18:03:55 EEST
Reason: MoldSign Signature
Location: Moldova

Mia Med
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