



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## Manufacturer

Name: MAR'CO, s.r.o. (Ltd.)  
Address: ul. 9. mája 15, 917 02 Trnava, Slovakia  
SRN:

## Product Information

Name: ORTHOPEDIC BELT  
Model: MM007 or customized  
EMDN: Y093303  
Basic UDI: /  
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Conformity Assessment

### Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971:2019  
EN ISO 15223-1:2021  
EN ISO 20417: 2021  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-V9099-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date:2022-10-24

Position: GM

Place: SLOVAKIA