



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Manufacturer

Name: MAR'CO, S.R.O.

Address: Ul. 9. Maja 15 91702 Trnava SLOVAKIA

SRN:

Product Information

Name: Orthopedic lumbar belt BackieBelt

Model: BB001

EMDN: Y060308

Basic UDI: 08588008909BackieBeltU3

Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

Intended purpose: Providing lumbar support through mechanical stabilization and compression.

Declaration

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The device that is covered by the present declaration is in conformity with the Regulation (EU) 2017/745 and the applicable standards above.

Signature: JUDr. Július Šefčík Date: 11.12.2025

Position: konateľ

Place: SLOVAKIA

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 13485:2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y093303-01.

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.