

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: HuiZhouShi YiHuKang Trading Co. Ltd.
No.105 ,JinFuYuan, NanEr Rd., XinNa ,
XinWuXiaoZu ,Bogang Village, XiaoJinKou Street,
HuiCheng District ,Huizhou City,Guangdong, China

Trademark: N.A

SRN: CN-MF-000043902

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: N.A

Product name: Rotating Seat Cushion

Product code / Catalogue number: See model list

Basic UDI: (01)06975802073016

Classification acc. to MDR Ax. VIII: Class I, Rule 1

Applied Standard & Common Specification: EN ISO 14971:2019、EN ISO 15223-1:2021、EN ISO 20417:2021、EN 62366-1:2015

Conformity assessment procedure: Annex II + Annex III, Annex IV of MDR

CE certificate No.: N.A

Name and ID of the Notified Body: N.A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

刘城

Liu Cheng,
General Manager

Huizhou, Guangdong, 20. 09. 2023

Model/Type/specification

Part/Catalogue Number	Description/Name	GMDN Code
Rotating Seat Cushion FC150026-S	Rotating Seat Cushion	37163
Rotating Seat Cushion FC150026-M	Rotating Seat Cushion	37163
Rotating Seat Cushion FC150026-L	Rotating Seat Cushion	37163
Rotating Seat Cushion FCP150026-S	Rotating Seat Cushion	37163
Rotating Seat Cushion FCP150026-M	Rotating Seat Cushion	37163
Rotating Seat Cushion FCP150026-L	Rotating Seat Cushion	37163
Rotating Stand Cushion FC150030	Rotating Seat Cushion	37163