

EU DECLARATION OF CONFORMITY

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

Manufacturer: Nantong Yeming Textile Technology Co., Ltd.
Building 1, Group 20, Tangfang village, Zhangzhishan Town
Tongzhou District, Nantong City, Jiangsu Province, China

Trademark: EvoluXion

SRN: CN-MF-000032788

European Representative: Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland

SRN: NL-AR-000002066

Trade name: Memory foam seat cushion

Product name: Memory foam seat cushion

Product models: EvoGel EV700 and EvoVisco EV800

Basic UDI-DI: 697523765EvoGelHB

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

Applied Standard & Common Specification: EN ISO 13485:2016, EN ISO 14971:2021, EN ISO 15223-1:2016, EN ISO 10993-5:2009, EN ISO 10993-10:2021

Conformity assessment procedure: Annex II + Annex III of MDR

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.

Signature:

Title:

Position:

Place:

Date:

Luji
Production Manager
China
2023.3.16

