## **EC Declaration of Conformity**

Manufacturer:

Hunan Xiangzi Medical Devices Technology Co., Ltd. Address: 2th Floor, Building 6, Phase 2 Longling Electronic Industry Park, Heshan District, Yiyang City 413000, Hunan Province, China. EU Authorized Representative:

MedPath GmbH

Address:Mies-van-der-Rohe-Strasse 8,

80807 Munich,Germany

We, the manufacturer, herewith declare that the products

## **Medical Varicose Compression Stockings**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to Class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

The product concerned has been following the conformity assessment route according to Annex VII of Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC).

Standards applied:

EN ISO13485:2016

EN ISO14971:2012

EN1041:2008

EN980:2008

ISO10993-5:2009

ISO10993-10:2010

EN62366:2008

ENV12718:2001

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of Company: Hunan Xiangzi Medical Devices Technology Co., Ltd.

Address: 2th Floor, Building 6, Phase 2 Longling Electronic Industry Park, Heshan District, Yiyang City 413000, Hunan Province, China.

Yiyang, 2021-02-09

Place, date

Yongjie Zou

Yongjie Zou, Manager

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