

EU DECLARATION OF CONFORMITY

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

Manufacturer: WUHAN TOPMED TRADING CO., LTD
C5-1203,Rongchuangzhigu,No.555 Cultural Avenue, Hongshan District, Wuhan, Hubei, China

Trademark: N.A.

Manufacturer's SRN: CN-MF-000018876

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 München, GERMANY

European Representative's SRN: DE-AR-000000087

Trade name: Disposable Pants

Product name: Examination Pants

Basic UDI-DI: 697047515M20028Q

EMDN CODE: T0299

Intended Use: For patient examination use

Ref No . M2002

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

Applied Standard & Common Specification: EN ISO13485:2016, EN ISO 14971:2019/A11:2021, EN ISO10993-1:2020, EN ISO10993-5:2009, EN ISO10993-10:2023, EN ISO 10993-23:2021, EN ISO 15223-1:2021, EN ISO 20417: 2021, EN 62366-1: 2015+A1:2020

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

Rong Zhu / General manager

China Wuhan, Jun 14, 2023

