

UK DECLARATION OF CONFORMITY

Manufacturer: Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.
No. 316, National Road, Xinju, Changshan Town, Jinxian County, Nanchang City, 331724 Jiangxi, P.R. China.

UK Responsible Person: MedPath Limited
27 Old Gloucester Street,
London, United Kingdom, WC1N 3AX

Product name: Sterile Latex Examination Gloves for Single Use

Type/specification: Type: powder-free textured, powder-free smooth
Specification: XS, S, m, M, U, L, XL

Classification acc. to MDD Ax. IX: Class Is, rule 1

Applied Standards: EN455-1.2.3

Conformity assessment procedure: MDD Annex VII+V

Name and ID of the Notified Body/Approved Body: TUV Rheinland LGA Products GmbH 0197

Certificate No.: DD 60135681 0001

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of current effective UK Medical Devices Regulations 2002 and the amendments, and the Directive 93/42/EEC on Medical Devices (MDD), amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Che Xuemei,
Manager Representative

Jiangxi, 7.1. 2022

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UK Responsible Person: MedPath Limited
27 Old Gloucester Street,
London, United Kingdom, WC1N 3AX

Product name: Sterile Latex Surgical Gloves for Single Use

Type/specification: Type: powder-free textured, powder-free smooth
Specification: 6, 6.5, 7, 7.5, 8, 8.5

Classification acc. to MDD Ax. IX: Class IIa, rule 7

Applied Standards: EN455-1.2.3

Conformity assessment procedure: MDD Annex VII+V

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27 Old Gloucester Street,
London, United Kingdom, WC1N 3AX

Product name: Examination Gloves

Type/specification: Type: Type A (latex gloves); Type C (nitrile gloves);
Type D (PVC gloves) / Specification: XS, S, M, L, XL

Classification acc. to MDD Ax. IX: Class I, rule 1

Applied Standards: EN455-1.2.3

Conformity assessment procedure: MDD Annex VII

Name and ID of the Notified Body/Approved Body: N.A

Certificate No.: N.A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of current effective UK Medical Devices Regulations 2002 and the amendments, and the Directive 93/42/EEC on Medical Devices (MDD), amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

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