EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

Registration No.: DD 60135681 0001

Report No.: 15096321 002

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

Products:
Sterile Latex Surgical Gloves for Single Use;

Aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Latex Examination Gloves for Single Use

Expiry Date: 2023-10-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-03-05

Date: 2020-03-05

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.:	DZ 2113818-1
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
EUDAMED Single Registration No.:	CN-MF-000015523
Products:	Products of class Is: T020604- MEDICAL USE FACE MASKS, TYPE II AND IIR -Disposable Medical Surgical Masks T0207-CAPS AND HEADWEAR (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) -Disposable Surgical Caps T020401-STANDARD SURGICAL GOWNS -Disposable Surgical Gowns The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
Authorised representative(s):	CMC Medical Devices & Drugs, S.L. C/Horacio Lengo N° 18, CP 29006, Málaga-Spain

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-05-24

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	244360513-200
Effective date:	2022-05-24
Expiry date:	2027-03-30
Issue date:	2022-05-24

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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