EC CERTIFICATE

Number: 6048797CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Guilin HBM Health Protections, Inc.

No.1-2, Shuijing East Road, Economic and Technological Development Area
541805 Guilin, Guangxi
China

For the product category(ies)

Latex Condoms in application for contraception and for prophylactic purposes, Surgical Gloves

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 6048309CN, initially dated 10 March 2020
Addendum, initially dated 16 June 2020

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 16 June 2020
Revised: 2 March 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 6048797CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Latex Condoms in application for contraception and for prophylactic purposes,
Surgical Gloves

Issued to:

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area
541805 Guilin, Guangxi
China

This certificate covers the following product(s):

Surgical gloves

- Natural rubber latex gloves
- Polyisoprene rubber latex gloves

Latex Condoms

- smooth surface Latex Male Condoms
- non smooth surface Latex Male Condoms

Initial date: 16 June 2020
Revision date: 2 March 2021

DEKRA Certification B.V.

B.T.M. Holtus
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GUILIN HBM HEALTH PROTECTIONS, INC.
No.1-2, Shuijing East Road, Economic and
Technological Development Area, Guilin, China
Phone: 0773-2550119 www.hbmchina.com

EC Declaration of Conformity

Manufacturer
Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin, China

Brand name and model	Description of the Products	Classification
Meditrade Gentle Skin® Superior OP *REF: 904155* *REF: 904160* *REF: 904165* *REF: 904170* *REF: 904175* *REF: 904180* *REF: 904185* *REF: 904190*	Sterile Latex Surgical Gloves, Disposable, Powder Free	Class IIa (According to MDD 93/42/EEC, Annex IX, rule 6)

Conformity Assessment Route : MDD 93/42/EEC Annex II excluding 4

We herewith declare that the above-mentioned products meet the provisions of the EC Council Directive 93/42/EEC concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Notified Body: DEKRA Certification B.V.
Meander 1051 6825 MJ Arnhem P.O. Box 5185
6802 ED Arnhem The Netherlands

Notified Body's ID No 0344

EC Certificate No: 6048797CE01
EC Certificate Valid From: 16 June 2020
EC Certificate Valid Until: 26 May 2024
European Representative: HBM Medical
Coliemore House, Coliemore Road, Dalkey, Co Dublin, Ireland

Place, Date of issue: Guilin

SIGNATURE: FEB.09, 2022

Tiger Hu
General Manager
For and on behalf of Guilin
HBM Health Protections, Inc.