

# 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

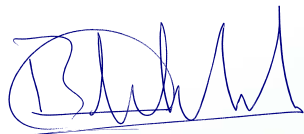
Documents, that form the basis of this certificate:

**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

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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  
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# ADDENDUM

Belonging to certificate: 6048797CE01

1/1

## 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

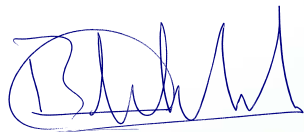
Latex Condoms

- 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.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name 'A. van Vugt'.

J.A. van Vugt  
Certification Manager

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## 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.