

EU Declaration of Conformity

Legal Manufacturer:

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and
Technological Development Area, Guilin, China
SRN: CN-MF-000033439

EU Authorized Representative:

HBM Medical
Coliemore House, Coliemore Road,
Dalkey, Co. Dublin, Ireland.
SRN: IE-AR-000031279

Brand owner:

Lohmann & Rauscher International GmbH & Co. KG
Westerwaldstraße 4
D-56579 Rengsdorf

Hereby declare in our own responsibility that the product:

Polyisoprene Surgical Gloves, sterile

Intended purpose: The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

(article numbers see attachment I)

(1)

are in conformity with Regulation (EU) 2017/745 on medical devices

meeting the provisions of EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 and ASTM D3577-19

Class IIa, Rule 7

Conformity assessment: Regulation (EU) 2017/745, Annex IX; Chapters I and III

Basic UDI-DI: 697178707SGPIU3

UMDNS Code: 11883

CND code: T01010203 SURGICAL GLOVES, Synthetic Polyisoprene

EMDN Code and Description: T01010203 Polyisoprene Surgical Gloves

Notified body:

BSI Group The Netherlands B.V. Say Building,

John M. Keynesplein 9,

1066 EP, Amsterdam, Netherlands

Notified Body Number: 2797

Certificate No: MDR 747912 R000

(2)

**are in conformity with Personal Protective Equipment Regulation (EU) 2016/425,
under Category III risk set out in Annex I**

meeting the provisions of EN ISO 21420:2020, EN ISO 374-1:2016 + A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374- 5:2016.

The products are subject to the procedure set out in:
Annex V (EU type examination) and Annex VIII (Module D) of Regulation (EU) 2016/425 issued by

Notified Body:

SATRA Technology Europe Limited
Bracetown Business Park Clonee, D15 YN2P, Ireland

Notified Body Number: 2777

EU type-examination certificate No: 2777/23740-02/E00-00

Huang Shun / Quality Director & PRRC

Place/date: Guilin, China, 2025-04-27

ATTACHMENT I

Guilin HMB Article Number	Guilin HMB Product name	Corresponding L&R Article Number	L&R Product name
MPIG55	Polyisoprene surgical glove	400740	Sentinex® Surgical PI Essential 5.5
MPIG60	Polyisoprene surgical glove	400741	Sentinex® Surgical PI Essential 6
MPIG65	Polyisoprene surgical glove	400742	Sentinex® Surgical PI Essential 6.5
MPIG70	Polyisoprene surgical glove	400743	Sentinex® Surgical PI Essential 7
MPIG75	Polyisoprene surgical glove	400744	Sentinex® Surgical PI Essential 7.5
MPIG80	Polyisoprene surgical glove	400745	Sentinex® Surgical PI Essential 8
MPIG85	Polyisoprene surgical glove	400746	Sentinex® Surgical PI Essential 8.5
MPIG90	Polyisoprene surgical glove	400747	Sentinex® Surgical PI Essential 9
MPUG55	Polyisoprene surgical underglove	400750	Sentinex® Surgical PI Underglove 5.5
MPUG60	Polyisoprene surgical underglove	400751	Sentinex® Surgical PI Underglove 6
MPUG65	Polyisoprene surgical underglove	400752	Sentinex® Surgical PI Underglove 6.5
MPUG70	Polyisoprene surgical underglove	400753	Sentinex® Surgical PI Underglove 7
MPUG75	Polyisoprene surgical underglove	400754	Sentinex® Surgical PI Underglove 7.5
MPUG80	Polyisoprene surgical underglove	400755	Sentinex® Surgical PI Underglove 8
MPUG85	Polyisoprene surgical underglove	400756	Sentinex® Surgical PI Underglove 8.5
MPUG90	Polyisoprene surgical underglove	400757	Sentinex® Surgical PI Underglove 9