

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:

Continental Medical B.V.
Strevelsweg 700 303 Unit E7288, 3083 AS
Rotterdam, Netherlands
SRN: NL-AR-000022261

Brand owner:

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

Hereby declare in our own responsibility that the product:

Latex Surgical Gloves, sterile

Intended purpose: The surgical gloves are single use devices in sterile condition, intended to be worn on the hands of operating room personnel, to protect the patient and the surgeon against contamination and also to provide a barrier for the wearer against potentially infectious material or different chemicals used within the healthcare sector. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility and are designed for use in the environments within hospitals and other healthcare facilities.

(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: 697178707SGNRUF

UMDNS Code: 11883

CND code: T01010202 SURGICAL GLOVES, LATEX

EMDN Code and Description: T01010102 - NON-POWDERED LATEX 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, EN 421:2010 (Radioactive contamination only)

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: 2777/27540-01/E00-00



Shun Huang

Huang Shun / Quality Director & PRRC

Place/date: Guilin, China, 2026-01-13

ATTACHMENT I

Guilin HMB Article Number	Guilin HMB Product name	Corresponding L&R Article Number	L&R Product name
MLES55	Essential latex surgical gloves	400700	Sentinex® Latex Essential 5.5
MLES60	Essential latex surgical gloves	400701	Sentinex® Latex Essential 6
MLES65	Essential latex surgical gloves	400702	Sentinex® Latex Essential 6.5
MLES70	Essential latex surgical gloves	400703	Sentinex® Latex Essential 7
MLES75	Essential latex surgical gloves	400704	Sentinex® Latex Essential 7.5
MLES80	Essential latex surgical gloves	400705	Sentinex® Latex Essential 8
MLES85	Essential latex surgical gloves	400706	Sentinex® Latex Essential 8.5
MLES90	Essential latex surgical gloves	400707	Sentinex® Latex Essential 9