# 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:

**Latex 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.

| Product code | Product description |
|---|---|
| 400710 -400717 | Sentinex® Latex Pro, size 5.5 through to 9, cream/transparent coloured |
| 400720 -400727 | Sentinex® Latex Touch, size 5.5 through to 9, cream coloured |
| 400730 -400737 | Sentinex® Latex Underglove, size 5.5 through to 9, green coloured |
| 400700 -400707 | Sentinex® Latex Essential, size 5.5 through to 9, white coloured |

**（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: XXX

Huang Shun

Huang Shun, Quality Manager & PRRC

Place/date: Guilin, China, 2025-11-26