

**IDEAL MEDICAL INDUSTRIES CO., LTD.**

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**Ideal Sterile Latex Surgical Gloves****Certificate of Analysis**

Powdered

|                        |                  |                                |                                                                                                          |                         |                   |
|------------------------|------------------|--------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------|-------------------|
| Product Name           |                  | Powdered Latex Surgical Gloves | Product Standard                                                                                         |                         | EN455-1, -2-3     |
| Lot No.                |                  | 20190720                       | Type, Size                                                                                               |                         | 6.6.5, 7.7.5, 8   |
| MFG. date              |                  | 07/2019                        | EXP. date                                                                                                |                         | 06/2024           |
| Lot Quantity           |                  | 500000 pairs                   | Sample Quantity                                                                                          |                         | 315 pairs         |
| Sampling               |                  | 22-07-19~23-07-19              | Test Date                                                                                                |                         | 23-07-19~29-07-19 |
| Sampler                |                  | Mike Lee                       | Identifier                                                                                               |                         | Mike Lee          |
| <b>Test Item</b>       |                  | <b>Index</b>                   | <b>Test Level</b>                                                                                        | <b>Test Result</b>      | <b>Result</b>     |
| Before Aging           | Tensile Strength | ≥12 N                          | S-2 AQL 1.5                                                                                              | 16.0~19.1, 0/13         | Pass              |
| Aged                   | Tensile Strength | ≥9 N                           | S-2 AQL 1.5                                                                                              | 13.2~15.0, 0/13         | Pass              |
| 6#                     | Length           | ≥260 mm                        | S-2 AQL 1.5                                                                                              | 263~268, 0/13           | Pass              |
|                        | Width            | 77±5mm                         | S-2 AQL 1.5                                                                                              | 75~80, 0/13             | Pass              |
|                        | Thickness        | ≥0.10mm                        | S-2 AQL 1.5                                                                                              | 0.28~0.31, 0/13         | Pass              |
| 6.5#                   | Length           | ≥260 mm                        | S-2 AQL 1.5                                                                                              | 266~272, 0/13           | Pass              |
|                        | Width            | 83±5mm                         | S-2 AQL 1.5                                                                                              | 82~86, 0/13             | Pass              |
|                        | Thickness        | ≥0.10mm                        | S-2 AQL 1.5                                                                                              | 0.28~0.31, 0/13         | Pass              |
| 7#                     | Length           | ≥270 mm                        | S-2 AQL 1.5                                                                                              | 272~276, 0/13           | Pass              |
|                        | Width            | 89±5mm                         | S-2 AQL 1.5                                                                                              | 88~92, 0/13             | Pass              |
|                        | Thickness        | ≥0.10mm                        | S-2 AQL 1.5                                                                                              | 0.28~0.31, 0/13         | Pass              |
| 7.5#                   | Length           | ≥270 mm                        | S-2 AQL 1.5                                                                                              | 273~279, 0/13           | Pass              |
|                        | Width            | 95±5mm                         | S-2 AQL 1.5                                                                                              | 93~99, 0/13             | Pass              |
|                        | Thickness        | ≥0.10mm                        | S-2 AQL 1.5                                                                                              | 0.28~0.31, 0/13         | Pass              |
| 8#                     | Length           | ≥275 mm                        | S-2 AQL 1.5                                                                                              | 280~282, 0/13           | Pass              |
|                        | Width            | 102±6mm                        | S-2 AQL 1.5                                                                                              | 99~105, 0/13            | Pass              |
|                        | Thickness        | ≥0.10mm                        | S-2 AQL 1.5                                                                                              | 0.28~0.31, 0/13         | Pass              |
| Leachable Protein      |                  | 200µg/dm <sup>2</sup>          | 3 pcs                                                                                                    | 80.0 µg/dm <sup>2</sup> | Pass              |
| Freedom from holes     |                  |                                | G-1 AQL1.5                                                                                               | 0/315                   | Pass              |
| Labeling               |                  |                                | S-2 AQL 1.5                                                                                              | 0/13                    | Pass              |
| sterilize result       |                  |                                | N/A                                                                                                      | A                       | Pass              |
| Biological Test        |                  |                                | Non-Irritation to Rabbit's Skin and Non-sensitization to Guinea Pig's Skin.                              |                         |                   |
| Determinant Compliance |                  |                                | This lot conforms to the requirements established by the specifications of EN455-1, EN455-2 and EN455-3. |                         |                   |

David Qiu

Approved By

David Qie/ QC Dept.



SX60009178000



J03Q10203R0S

# 扬州辐照中心

YANGZHOU IRRADIATION CENTER

地址：江苏省扬州市扬子江北路 568 号

ADDRESS: 568# YANGZIJIANG NORTH ROAD, YANGZHOU JIANGSU PROVINCE

## 辐照证明

### CERTIFICATE OF IRRADIATION

客户名称 CUSTOMER: IDEAL MEDICAL INDUSTRIES CO., LTD.

辐照日期 RADIATION DATE: 2019.07.20-2019.07.21

产品名称 DESCRIPTION: LATEX SURGICAL GLOVES

产品批号 PRODUCTS LOT No.: 20190720

辐照箱数 QUANTITY: 1000 CTNS

客户要求剂量 STERILIZATION DOSE REQUIRED BY CUSTOMER:

最低剂量 MIN.DOSE: 25 KGY

最高剂量 MAX.DOSE: 40 KGY

该产品经  $^{60}\text{Co}$ -射线辐照:

The commodity mentioned above has been irradiated by  $^{60}\text{Co}$ -ray

产品实际最低剂量 (Minimum absorbed dosage) : 25.2 kGY

产品实际最高剂量 (Maximum absorbed dosage) : 38.6 kGY

产品有效期 (Expiry date) : 06/2024

签发 (Issued by): wang xing hai

日期 (Date): 2019.07.22

YANGZHOU IRRADIATION CENTER

