

# JIS

JAPANESE  
INDUSTRIAL  
STANDARD

Translated and Published by  
Japanese Standards Association

---

---

**JIS T 9107** : 2018

(JGMA/JSA)

**Single-use sterile rubber surgical  
gloves—Specification**

---

ICS 11.040;11.140;83.140.99

Reference number : **JIS T 9107 : 2018 (E)**

T 9107 : 2018

Date of Establishment: 2000-03-27

Date of Revision: 2018-03-01

Date of Public Notice in Official Gazette: 2018-03-01

Investigated by: Japanese Industrial Standards Committee  
Standards Board for ISO area  
Technical Committee on Medical Equipment

---

JIS T 9107:2018, First English edition published in 2018-12

Translated and published by: Japanese Standards Association  
Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

---

In the event of any doubts arising as to the contents,  
the original JIS is to be the final authority.

© JSA 2018

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

KK/AT

PROTECTED BY COPYRIGHT

## Contents

|                                                                                                       | Page |
|-------------------------------------------------------------------------------------------------------|------|
| Introduction .....                                                                                    | 1    |
| 1 Scope .....                                                                                         | 1    |
| 2 Normative references .....                                                                          | 1    |
| 3 Terms and definitions .....                                                                         | 1    |
| 4 Classification .....                                                                                | 2    |
| 4.1 Type .....                                                                                        | 2    |
| 4.2 Design .....                                                                                      | 2    |
| 4.3 Surface finish .....                                                                              | 3    |
| 5 Materials .....                                                                                     | 3    |
| 5.1 Main materials .....                                                                              | 3    |
| 5.2 Sub materials .....                                                                               | 3    |
| 5.3 Biological safety .....                                                                           | 3    |
| 6 Quality .....                                                                                       | 4    |
| 6.1 Size code and dimensions .....                                                                    | 4    |
| 6.2 Watertightness (pinhole test) .....                                                               | 4    |
| 6.3 Properties (tensile properties) .....                                                             | 4    |
| 6.4 Residual powder .....                                                                             | 5    |
| 7 Sampling and selection of test pieces .....                                                         | 5    |
| 8 Measurement and test methods .....                                                                  | 5    |
| 8.1 Measurement of dimensions .....                                                                   | 5    |
| 8.2 Watertightness test (pinhole test) .....                                                          | 6    |
| 8.3 Properties test (tensile properties) .....                                                        | 6    |
| 8.4 Residual powder test .....                                                                        | 7    |
| 9 Sterilization .....                                                                                 | 7    |
| 10 Packaging .....                                                                                    | 7    |
| 11 Marking .....                                                                                      | 7    |
| 11.1 Body of gloves .....                                                                             | 7    |
| 11.2 Inner package of gloves .....                                                                    | 7    |
| 11.3 Unit package of gloves .....                                                                     | 7    |
| 11.4 Multi-unit package of gloves .....                                                               | 8    |
| Annex A (normative) Watertightness test (pinhole test) .....                                          | 9    |
| Bibliography .....                                                                                    | 11   |
| Annex JA (informative) Comparison table between JIS and corresponding<br>International Standard ..... | 12   |

## Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Glove Manufacturers Association (JGMA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS A 9107:2011** is replaced with this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

# Single-use sterile rubber surgical gloves—Specification

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 10282:2014**, Edition 3, with some modifications of the technical contents according to the situation in Japan.

The dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

## 1 Scope

This Standard specifies requirements for single-use sterile rubber surgical gloves (hereafter referred to as gloves) intended for use in medical and dental surgical procedures to protect the patient and the user from cross-contamination.

**NOTE 1** JIS T 9107:2011 may be applied until February 28, 2021.

**NOTE 2** The International Standard corresponding to this standard and the symbol of degree of correspondence are as follows.

ISO 10282:2014 *Single-use sterile rubber surgical gloves—Specification*  
(MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are **IDT** (identical), **MOD** (modified), and **NEQ** (not equivalent) according to **ISO/IEC Guide 21-1**.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards indicated below, only the editions of the indicated year shall be applied and any revisions (including amendments) made thereafter shall not be applied.

JIS K 6250:2006 *Rubber—General procedures for preparing and conditioning test pieces for physical test methods*

**NOTE** Corresponding International Standard: ISO 23529 *Rubber—General procedures for preparing and conditioning test pieces for physical test methods*

JIS K 6251:2017 *Rubber, vulcanized or thermoplastic—Determination of tensile stress-strain properties*

**NOTE** Corresponding International Standard: ISO 37 *Rubber, vulcanized or thermoplastic—Determination of tensile stress-strain properties*

JIS K 6257:2010 *Rubber, vulcanized or thermoplastic—Determination of heat ageing properties*

**NOTE** Corresponding International Standard: ISO 188 *Rubber, vulcanized or thermoplastic—Accelerated ageing and heat resistance tests*