

# JIS

JAPANESE  
INDUSTRIAL  
STANDARD

Translated and Published by  
Japanese Standards Association

---

JIS T 3211-11 : 2019

(MTJAPAN/JSA)

**Sterile infusion administration set —  
Part 11: Sterile infusion filters for single  
use**

---

ICS 11.040.20

Reference number : JIS T 3211-11 : 2019 (E)

PROTECTED BY COPYRIGHT

10 S

T 3211-11 : 2019

Date of Establishment: 2019-03-01

Date of Public Notice in Official Gazette: 2019-03-01

Investigated by: Japanese Industrial Standards Committee

Standards Board for ISO area

Technical Committee on Medical Equipment

---

JIS T 3211-11 : 2019, First English edition published in 2019-12

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 2019

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/HN

PROTECTED BY COPYRIGHT

## Contents

	Page
Introduction .....	1
1 Scope .....	1
2 Normative references .....	1
2A Terms and definitions .....	2
3 Design .....	2
4 Materials .....	2
5 Physical requirements .....	2
5.1 Transparency .....	2
5.2 Particulate contamination .....	2
5.3 Tensile strength .....	2
5.4 Leakage .....	2
5.4A Pore size .....	2
5.5 Adapters with female and/or male conical fittings .....	3
5.6 Protective caps .....	3
6 Chemical requirements .....	3
7 Biological requirements .....	3
7.1 Sterility .....	3
7.2 Pyrogens .....	3
7.3 Haemolysis .....	3
8 Packaging .....	3
9 Labelling .....	3
9.1 General .....	3
9.2 Label on unit container .....	3
9.3 Label on shelf or multi-unit container .....	4
Annex A (normative) Physical tests .....	5
Annex B (normative) Chemical tests .....	6
Annex C (normative) Biological tests .....	7
Annex JA (informative) Evaluation of pore size of infusion filter .....	8
Annex JB (informative) Comparison table between JIS and corresponding International Standard .....	11

## Foreword

This Japanese Industrial Standard has been established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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 Minister 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.

**JIS T 3211** series consists of the following 7 parts under the general title *Sterile infusion administration set*:

*Part 4 : Sterile infusion sets for single use, gravity feed*

*Part 5 : Sterile burette infusion sets for single use*

*Part 8 : Sterile infusion sets for single use with pressure infusion apparatus*

*Part 9 : Sterile fluid lines for single use*

*Part 10 : Sterile accessories for fluid lines for single use*

*Part 11 : Sterile infusion filters for single use*

*Part 12 : Sterile check valves for single use*

# Sterile infusion administration set — Part 11 : Sterile infusion filters for single use

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-11:2015**, Edition 2, with some modifications of the technical contents to reflect the needs and conditions unique to Japan.

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

## 1 Scope

This Standard applies to sterile infusion filters for single use (hereafter referred to as infusion filters) intended for sterile infusion sets for single use (JIS T 3211-4 and JIS T 3211-8).

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

ISO 8536-11 : 2015 *Infusion equipment for medical use — Part 11 : Infusion filters for single use with pressure infusion equipment* (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 with the year indication, only the editions of the indicated year shall be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent edition (including amendments) shall be applied.

JIS T 3211-4 *Sterile infusion administration set — Part 4 : Sterile infusion sets for single use, gravity feed*

**NOTE** Corresponding International Standard : ISO 8536-4 *Infusion equipment for medical use — Part 4 : Infusion sets for single use, gravity feed* (MOD)

JIS T 3211-8 *Sterile infusion administration set — Part 8 : Sterile infusion sets for single use with pressure infusion apparatus*

**NOTE** Corresponding International Standard : ISO 8536-8 *Infusion equipment for medical use— Part 8: Infusion sets for single use with pressure infusion apparatus* (MOD)