



**NSAI**  
Standards

Irish Standard Recommendation  
S.R. CEN/TR 16953:2017

# Medical gloves for single use - Guidance for selection

© CEN 2017 No copying without NSAI permission except as permitted by copyright law.

**S.R. CEN/TR 16953:2017**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

CEN/TR 16953:2017

*Published:*

2017-11-15

*This document was published under the authority of the NSAI and comes into effect on:*

2017-12-03

*ICS number:*

11.140

*NOTE: If blank see CEN/CENELEC cover page*

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

S.R. CEN/TR 16953:2017 is the adopted Irish version of the European Document CEN/TR 16953:2017, Medical gloves for single use - Guidance for selection

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

# TECHNICAL REPORT

# CEN/TR 16953

## RAPPORT TECHNIQUE

## TECHNISCHER BERICHT

November 2017

ICS 11.140

English Version

### Medical gloves for single use - Guidance for selection

Gants médicaux non réutilisables - Lignes directrices  
pour sélectionner des gants médicaux non réutilisables

Medizinische Einmalhandschuhe - Leitlinien für die  
Auswahl

This Technical Report was approved by CEN on 22 October 2017. It has been drawn up by the Technical Committee CEN/TC 205.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## **Contents**

	Page
<b>European foreword.....</b>	<b>4</b>
<b>Introduction .....</b>	<b>5</b>
<b>1 Scope.....</b>	<b>6</b>
<b>2 Normative references.....</b>	<b>6</b>
<b>3 Terms and definitions .....</b>	<b>6</b>
<b>4 Considerations in glove selection.....</b>	<b>8</b>
<b>4.1 General.....</b>	<b>8</b>
<b>4.2 Cross contamination risk .....</b>	<b>9</b>
<b>4.2.1 General.....</b>	<b>9</b>
<b>4.2.2 Freedom from holes .....</b>	<b>9</b>
<b>4.2.3 Physical properties.....</b>	<b>10</b>
<b>4.2.4 Storage stability.....</b>	<b>10</b>
<b>4.3 Biocompatibility .....</b>	<b>11</b>
<b>4.3.1 General.....</b>	<b>11</b>
<b>4.3.2 Allergenic potential.....</b>	<b>11</b>
<b>4.3.3 Plasticisers.....</b>	<b>13</b>
<b>4.4 Potential contaminants.....</b>	<b>13</b>
<b>4.4.1 General.....</b>	<b>13</b>
<b>4.4.2 Glove Powder.....</b>	<b>13</b>
<b>4.4.3 Sterilisation residues (Endotoxins).....</b>	<b>14</b>
<b>4.4.4 Surface additives .....</b>	<b>14</b>
<b>5 Raw materials.....</b>	<b>14</b>
<b>5.1 Specific glove raw materials.....</b>	<b>14</b>
<b>5.1.1 Natural rubber .....</b>	<b>14</b>
<b>5.1.2 Synthetic rubber .....</b>	<b>14</b>
<b>5.1.3 Thermoplastics .....</b>	<b>14</b>
<b>5.2 Glove coating.....</b>	<b>14</b>
<b>6 Glove disinfection.....</b>	<b>15</b>
<b>7 Labelling.....</b>	<b>15</b>
<b>Annex A (informative) Glove materials and their use .....</b>	<b>16</b>
<b>Annex B (informative) Additional information.....</b>	<b>18</b>
<b>B.1 Double gloving.....</b>	<b>18</b>
<b>B.2 Food contact.....</b>	<b>18</b>
<b>B.3 Handling chemicals and chemotherapy drugs .....</b>	<b>18</b>
<b>B.4 Effects of creams or disinfectants on medical gloves.....</b>	<b>18</b>
<b>B.5 Classes of medical gloves.....</b>	<b>19</b>
<b>B.6 Sharp EU-Directive (2010/32/EEC).....</b>	<b>19</b>
<b>B.7 Cytotoxicity of medical gloves .....</b>	<b>19</b>
<b>B.8 Glove selection, use time and durability.....</b>	<b>19</b>



This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- Looking for additional Standards? Visit Intertek Inform Infostore
- Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation