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China Association for Medical Devices Industry

Standards Applicable to Groups

T/ CAMDI 107-2023

Disposable Non-woven Wrap for Medical Use

(Draft for approval)

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Preface

This document is in accordance with GB/T 1.1-2020 "Guidelines for Standardization Work No. 1 Part: Structure and Drafting Rules for Standardized Documents Drafting".

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents .

This document was proposed by the China Association for Medical Devices Industry.

This document is under the jurisdiction of the Standardization Technical Committee of the Medical Device Packaging Professional Committee of the China Medical Device Industry Association .

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Medical Disposable Non-woven Wrap

1 Scope

This document specifies the general performance requirements, performance requirements and test methods, marking, packaging, transportation, and other aspects of medical disposable Non-woven wraps. Transport and storage, information provided by the manufacturer.

This document applies to disposable Non-woven wrappings for medical use.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document . Only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies to this document. Piece.

GB/T 451.2-2002 Determination of basis weight of paper and board

GB/T 1545-2008 Determination of paper, paper board and pulp acidity or alkalinity of aqueous extracts

GB/T 2678.2-2021 Determination of paper, paper board and pulp, water-soluble chloride

GB/T 3917.3-2009 Tear properties of textile fabrics - Part 3: Determination of tear strength of trapezoidal test specimens

GB/T 5709-1997 Textiles Non-woven fabrics the term

GB/T 7408-2005 Data elements and exchange formats, information exchange, date and time representation

GB/T 7742.1-2005 Bursting properties of textile fabrics - Part 1: Determination of bursting strength and bursting expansion - Hydraulic method

GB/T 7974-2013 Determination of paper, paperboard and pulp blue light diffuse reflectance D65 brightness (diffuse/vertical method, outdoor daylight conditions)

GB/T 19633.1-2015 Packaging of terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

GB/T 24218.3-2010 Test methods for textiles, non-woven - Part 3: Determination of breaking strength and elongation at break (Strip Law)

GB/T 24218.15-2018 Test methods for textiles, non-woven - Part 15: Determination of air permeability

GB/T 24218.16-2017 Test methods for textiles, non-woven - Part 16 : Determination of resistance to water penetration (hydro-static pressure method) Pharmacopoeia of the People's Republic of China (2020 Edition) Volume IV

YY 0469-2011 Medical surgical masks

YY/T 0698.2-2022 Packaging materials for terminally sterilized medical devices Part 2: Requirements and test methods for sterilization wrapping materials

ISO 9198:2020 Determination of paper, board and pulp, water-soluble sulfates

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Non-woven

A material made of oriented or randomly arranged fibers bonded to each other by friction, cohesion or bonding or a combination of these methods .

Note: Paper, woven fabrics, knitted fabrics, tufted fabrics, stitchbonded fabrics with stitchbonding yarns and wet-felt are not included. The fibers used may be Natural or chemical fibers; may be staple, filament, or fibers formed on the spot.

[Source: GB/T 5709—1997 , 2.3.1, modified]

3.2 Non-woven wrap

On the basis of non-woven fabrics, according to different clinical needs, product to be made after being cut into different sizes or after secondary processing.

3.3 Performance level

Products are determined as "standard performance" according to some performance requirements

or “High Performance” performance level.

Note: Two performance levels are introduced for the product based on the material of the package, the mechanical stress and the weight it bears .

3.4 Standard performance

A classification of products used as packaging for terminally sterilized medical devices with various characteristics listed as basic performance requirements during sterilization.

3.5 High performance performance

Products used as packaging for terminally sterilized medical devices are classified as having tightened performance requirements for various characteristics during sterilization .

4 General performance requirements

4.1 The material shall be free of extractable matter and be odorless under specified conditions and shall not adversely affect the performance and safety of medical devices in contact with it .

Note: Since odour can be determined by common understanding, it is not necessary to use a standardized test method to measure odour.

4.2 The material should not have defects such as perforations, damage, tears, wrinkles or local uneven thickness that may affect the material's function.

4.3 Materials should have acceptable levels of cleanliness, particulate contamination, and linting.

4.4 Under the conditions of use, the material should not contain or release any toxic substances that could cause health hazards before, during or after sterilization.

5 Performance requirements and test methods

5.1 Non-woven wrapping cloth should not fade. The hot extract prepared according to GB/T 1545-2008 should be colorless when tested by color inspection method in the Pharmacopoeia of the People's Republic of China (2020)Four volumes 0901.

5.2 According to GB/T 451.2-2002 during the test, for non- woven fabric of one square meter, the average mass should be within ±5% of the manufacturer's nominal value.

5.3 According to GB/T 1545-2008, water extracts made by medium heat extraction, pH of non-woven fabric extracts should be no less than 5 and no greater than 8.

5.4 According to ISO 9198-2020 during the test, the sulfate content (calculated as sodium sulfate) of the hot extract prepared as GB/T 451.2-2002 should not exceed 0.25% (2500 mg/kg).

5.5 According to GB/T 2678.2-2021, when performing the test, chloride content of hot extract prepared as GB/T 1545-2008 (calculated as sodium chloride) should not exceed 0.05% (500 mg/kg).

5.6 According to GB/T 7974-2013, during test, due to the fluorescent whitening agent, D65 fluorescence brightness should not exceed 1%.

5.7 According to YY/T 0698.2-2022 Appendix A, setting the Non-woven bag on a place under ultraviolet light, 25cm away, the number of fluorescent spots greater than 1mm on each 0.01m 2 should not exceed 5.

5.8 Manufacturers should provide drape results and related test methods upon request.

Note: Test method can be checked in YY/T 0698.2-2022 Appendix B. GB/ T 23329-2009, ISO9073-9, GB/T 8942-2016.

5.9 According to GB/T 3917.3-2009, during test the longitudinal and transverse tearing strength of the non-woven fabric shall meet the requirements of Table 1.

5.10 According to GB/T 7742.1-2005, when testing the bursting strength of the non-woven fabric should comply with requirements of Table 1 .

5.11 According to GB/T 7742.1-2005, during the test, the wet bursting strength of the non-woven fabric shall comply with the requirements of Table 1.

5.12 According to GB/T 24218.3-2010, during the test, the longitudinal and transverse breaking strength of the non-woven fabric shall comply with the requirements of Table 1.

5.13 According to GB/T 24218.3-2010, during the test, the longitudinal and transverse wet breaking strength of the non-woven fabric shall comply with the requirements of Table 1 .

5.14 According to GB/T 24218.3-2010, during the test, the longitudinal and transverse elongation at break of the non-woven wrapping fabric shall comply with the requirements of Table 1.

5.15 According to GB/T 24218.16-2017, during the test, the hydro-static pressure of the non-woven fabric shall comply with the requirements of Table 1.

5.16 According to GB/T 24218.15-2018, during the test, the air permeability of the non-woven fabric should meet the requirements of Table 1.

5.17 According to YY 0469-2011 5.6.2, during the test, the particle filtration efficiency (PFE) of the Non-woven fabric should meet the requirements of Table 1.

Table 1 Performance requirements

<table>
<tr><td rowspan="3">Test items</td><td rowspan="3">Unit</td><td rowspan="3">Test methods</td><td colspan="4">Performance level</td></tr>
<tr><td colspan="2">Standard performance</td><td colspan="2">high performance</td></tr>
<tr><td>Vertical</td><td>Horizontal</td><td>Vertical</td><td>Horizontal</td></tr>
<tr><td>Tear strength</td><td>N</td><td>GB/T 3917.3-2009</td><td>≥40</td><td>≥20</td><td>≥50</td><td>≥30</td></tr>
<tr><td>Bursting strength</td><td>kPa</td><td>GB/T 7742.1-2005</td><td colspan="2">≥45</td><td colspan="2">≥65</td></tr>
<tr><td>Wet bursting strength</td><td>kPa</td><td>GB/T 7742.1-2005</td><td colspan="2">≥45</td><td colspan="2">≥65</td></tr>
<tr><td rowspan="2">Breaking strength</td><td rowspan="2">N</td><td rowspan="2">GB/T 24218.3-2010</td><td>Vertical</td><td>Horizontal</td><td>Vertical</td><td>Horizontal</td></tr>
<tr><td>≥80</td><td>≥45</td><td>≥110</td><td>≥65</td></tr>
<tr><td rowspan="2">Wet breaking strength</td><td rowspan="2">N</td><td rowspan="2">GB/T 24218.3-2010</td><td>Vertical</td><td>Horizontal</td><td>Vertical</td><td>Horizontal</td></tr>
<tr><td>≥80</td><td>≥45</td><td>≥110</td><td>≥65</td></tr>
<tr><td rowspan="2">Elongation at break</td><td rowspan="2">%</td><td rowspan="2">GB/T 24218.3-2010</td><td>Vertical</td><td>Horizontal</td><td>Vertical</td><td>Horizontal</td></tr>
<tr><td colspan="2">≥60</td><td colspan="2">≥60</td></tr>
<tr><td>hydrostatic pressure</td><td>cmH_2O</td><td>GB/T 24218.16-2017</td><td colspan="2">≥40</td><td colspan="2">≥50</td></tr>
<tr><td>Air permeability</td><td>L/m^2/s</td><td>GB/T 24218.15-2018</td><td colspan="2">≥100</td><td colspan="2">≥60</td></tr>
<tr><td>Particle filtration efficiency (PFE)</td><td>%</td><td>YY 0469-2011</td><td colspan="2">≥40</td><td colspan="2">≥60</td></tr>
<tr><td colspan="7">Note: Longitudinal direction is along the machine direction and transverse direction is cross direction.</td></tr>
</table>

6 Marking, packaging, transportation and storage

6.1 Logo

Each packaging unit should be marked with the following contents: product name, product batch number or production date, product specifications (weight per unit area, nominal sheet length and width, nominal coil width and length, and other contents that the enterprise considers necessary to mark), quantity, manufacturer name and address.

Note 1 Regulatory requirements apply to identification and may be modified in the future , such as the unique device identifier (UDI).

Note 2: For the use of identification symbols, pls check YY/T 046 6.1-2023.

6.2 Package

Product packaging materials should ensure that product quality is not damaged and easy to transport.

6.3 Transportation

During transportation, it should be kept away from light, water, moisture, pollution, damage and extrusion.

6.4 Storage

It should be stored in a ventilated, dry, light-proof and clean warehouse.

7 Manufacturer Information

In addition to 7th chapter in GB/T 19633.1-2015, the manufacturer should also provide the following information:

--Recommendations for special applications of medical disposable Non-woven wraps (e.g. sterile barrier systems, protective packaging, packaging systems system);

--the nature and extent of any perceived risks associated with the packaging material and/or system;

--Any information that may be required regarding the packaged device.

Note: National regulations requiring information to be provided by manufacturers may apply.

Appendix A

(Informative)

Differences from YY/T 0698.2-2022

Medical disposable Non-woven wrapping is a kind of directional or randomly arranged fibers connected by friction, cohesion or bonding or a combination of methods. Materials made by combining with each other are standard YY/T 0698.2-2022 Non-woven wrapping materials in terminally sterilized medical device packaging materials. In order to promote the use of disposable medical Non-woven as independent medical device packaging materials in the Chinese medical field, a special This document is prepared to provide guidance for clinical use and a basis for acceptable standards.

The differences between this document and YY/T 0698.2-2022 standards are as follows:

a) The product range is small, and only the requirements for non-woven wrapping fabrics are specified;

b) The application scope is small and only applicable to disposable medical Non-woven wraps;

c) Due to the above two reasons, the accuracy of physical performance requirements increases;

d) Some physical property test method standards are changed to the corresponding national standards for Non-woven;

e) Added new physical property requirements and test methods for air permeability and particle filtration efficiency (PFE);

f) Two performance levels are introduced for the product based on the material, mechanical stress and weight of the packaged medical devices: Standard Performance and high performance.

This document aims to standardize and promote the development and progress of the medical disposable Non-woven industry.