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**Sterile drainage catheters and  
accessory devices for single use**

*Sondes et dispositifs auxiliaires stériles de drainage non réutilisables*

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# Contents

	Page
<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Intended performance</b> .....	<b>3</b>
<b>5 General requirements</b> .....	<b>3</b>
5.1 Risk management.....	3
5.2 Biocompatibility.....	4
5.3 Detectability.....	4
5.4 Surface finish.....	4
5.5 Size designation.....	4
5.5.1 General.....	4
5.5.2 Outer diameter.....	4
5.5.3 Effective length.....	4
5.5.4 Nominal balloon inflation volume.....	5
5.6 Connector.....	5
5.7 MRI compatibility.....	6
5.8 Sterilization.....	6
<b>6 Specific requirements</b> .....	<b>6</b>
6.1 Kink stability.....	6
6.2 Corrosion resistance.....	6
6.3 Resistance to deformation.....	6
6.4 Peak tensile force.....	6
6.4.1 Connections.....	6
6.4.2 Drainage catheters and other accessory devices.....	7
6.5 Impact resistance.....	7
6.6 Flow rate.....	7
6.7 Retention strength.....	7
6.8 Balloon safety.....	7
6.9 Drainage catheter inflation lumen integrity and volume maintenance.....	8
6.9.1 General.....	8
6.9.2 Compliant balloon.....	8
6.9.3 Non-compliant balloon.....	8
6.10 Inflated balloon resistance to traction.....	8
6.11 Freedom from leakage during aspiration or vacuum.....	8
<b>7 Information supplied by the manufacturer</b> .....	<b>9</b>
7.1 General.....	9
7.2 Marking on the device and/or packaging.....	9
7.3 Instructions for use.....	9
<b>Annex A (informative) Test method for determining kink stability</b> .....	<b>11</b>
<b>Annex B (normative) Test method for corrosion resistance</b> .....	<b>13</b>
<b>Annex C (normative) Test method for resistance to deformation by suction</b> .....	<b>14</b>
<b>Annex D (normative) Test method for determining peak tensile force of connections</b> .....	<b>15</b>
<b>Annex E (normative) Test method for determining peak tensile force of drainage catheter</b> .....	<b>16</b>
<b>Annex F (normative) Test method for impact resistance of collection device</b> .....	<b>18</b>
<b>Annex G (normative) Test method for determination of flow rate through drainage catheter</b> .....	<b>20</b>
<b>Annex H (informative) Test method for retention strength</b> .....	<b>22</b>

<b>Annex I (normative) Test method for determining balloon safety</b> .....	<b>24</b>
<b>Annex J (normative) Test method for determining inflation lumen leakage and/or function and/or balloon deflation (drainage catheter with compliant balloon)</b> .....	<b>27</b>
<b>Annex K (normative) Test method for determining balloon size and deflation reliability (drainage catheter with non-compliant balloon)</b> .....	<b>29</b>
<b>Annex L (normative) Test method for determining inflated balloon resistance to traction</b> .....	<b>31</b>
<b>Annex M (normative) Test method for resistance to leakage during aspiration or vacuum</b> .....	<b>35</b>
<b>Bibliography</b> .....	<b>37</b>

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This document is based on EN 1617, *Sterile drainage catheters for single use*.

This corrected version of ISO 20697:2018 incorporates the following corrections:

- correction of measurements and units in [6.9.3](#), [6.10](#), [H.2.2 a\)](#) and [L.2.1](#);
- deletion of EN 980 from Bibliography;
- minor editorial changes.

## Introduction

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

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