

---

---

**Catheter systems for neuraxial  
application — Sterile and single-use  
catheters and accessories**

*Systèmes de cathéters pour application neuraxiale — Cathéters et  
accessoires stériles et à usage unique*

**iTeh Standards**  
**(<https://standards.itih.ai>)**  
**Document Preview**

[ISO 20698:2018](https://standards.itih.ai/catalog/standards/iso/70291b00-2ba5-49e0-85ef-181596645300/iso-20698-2018)

<https://standards.itih.ai/catalog/standards/iso/70291b00-2ba5-49e0-85ef-181596645300/iso-20698-2018>



**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

ISO 20698:2018

<https://standards.iteh.ai/catalog/standards/iso/70291b00-2ba5-49e0-85ef-181596645300/iso-20698-2018>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# 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>2</b>
<b>4 Intended performance</b> .....	<b>4</b>
<b>5 Design attributes</b> .....	<b>4</b>
5.1 Nominal size of the catheter.....	4
5.1.1 General.....	4
5.1.2 Outside diameter.....	4
5.1.3 Catheter lengths.....	4
5.2 Catheter holes.....	4
5.3 Distal tip.....	4
5.4 Surface.....	5
5.5 Hubs.....	5
5.6 Markings.....	5
5.7 Filter.....	5
5.8 Stylet.....	5
5.9 Detectability.....	5
5.10 Fixation devices.....	5
<b>6 Materials</b> .....	<b>5</b>
6.1 General.....	5
6.2 Biocompatibility.....	6
6.3 Drug and material compatibility.....	6
<b>7 Design evaluation</b> .....	<b>6</b>
7.1 General.....	6
7.2 Pre-clinical evaluation.....	6
7.2.1 General.....	6
7.2.2 Radiopacity.....	6
7.2.3 Magnetic resonance compatibility.....	6
7.2.4 Corrosion resistance.....	6
7.2.5 Flow rate.....	7
7.2.6 Freedom from leakage (design).....	7
7.2.7 Peak tensile force.....	7
7.2.8 Catheter kinking test.....	7
7.2.9 Surface.....	7
7.3 Clinical evaluation.....	7
<b>8 Sterilization</b> .....	<b>7</b>
8.1 General.....	7
8.2 Sterilization residuals.....	8
<b>9 Packaging</b> .....	<b>8</b>
<b>10 Information to be supplied by the manufacturer</b> .....	<b>8</b>
10.1 Marking on the device.....	8
10.2 Information on instructions for use and/or packaging.....	8
<b>Annex A (normative) Test method for resistance to corrosion</b> .....	<b>9</b>
<b>Annex B (normative) Determination of flow rate through catheter</b> .....	<b>11</b>
<b>Annex C (normative) Test method for liquid leakage under pressure</b> .....	<b>14</b>
<b>Annex D (normative) Method for determining peak tensile force</b> .....	<b>16</b>

<b>Annex E (informative) Other units of measurement</b> .....	<b>18</b>
<b>Bibliography</b> .....	<b>20</b>

**iTeh Standards**  
**(<https://standards.itih.ai>)**  
**Document Preview**

[ISO 20698:2018](https://standards.itih.ai/catalog/standards/iso/70291b00-2ba5-49e0-85ef-181596645300/iso-20698-2018)

<https://standards.itih.ai/catalog/standards/iso/70291b00-2ba5-49e0-85ef-181596645300/iso-20698-2018>