

## TECHNICAL DATA



### B. Braun Stoma Care Belt

<b>1. Administrative information about B. Braun</b>		
<b>1.1</b>	<b>Name :</b> B. Braun Medical SAS	
<b>1.2</b>	<b>Status:</b> <b>Manufacturer :</b> B. Braun Medical SAS <b>France</b>	B. Braun Medical SAS 204 Avenue du Maréchal Juin 92100 – Boulogne-Billancourt FRANCE <a href="http://www.bbraun.com">www.bbraun.com</a> Tel: +331 41 10 53 00
<b>1.3</b>	<b>Quality system certification :</b> B. Braun Medical SAS Quality system complies with ISO 9001: 2008 ; ISO 13485: 2012 ; ISO 14 001: 2004  <b>Certificating body :</b> TÜV Product Service GmbH (0123)	

2. Information on the medical device											
2.1	<u>Trademark</u>		B. Braun								
	<u>Commercial name:</u>		B. Braun Stoma Care Belt								
2.2	<u>Indications</u>										
	For fixing the Iryflex® faceplate on the skin or the convex 1-piece pouches or 2-pieces base plates										
2.3	<u>Product description</u>										
	Belt for fixation of faceplate or convex 1-piece pouches or 2-piece base plates										
	<u>Features</u>										
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2.4	<u>References</u>										
	<u>References</u>	<u>Nominal dimensions</u>	<u>Packaging</u>								
	5028	L: 120 cm W: 4 cm	1 Pc								
2.5	<u>Constituent elements of the product</u>										
	<table border="1"> <thead> <tr> <th>Components</th> <th>Materials</th> </tr> </thead> <tbody> <tr> <td>Belt</td> <td>• Elastane +polyamide (PA)</td> </tr> <tr> <td>Hook</td> <td>• Polyethylene (PE)</td> </tr> <tr> <td>Loop</td> <td>• Polyamide (PA)</td> </tr> </tbody> </table>			Components	Materials	Belt	• Elastane +polyamide (PA)	Hook	• Polyethylene (PE)	Loop	• Polyamide (PA)
Components	Materials										
Belt	• Elastane +polyamide (PA)										
Hook	• Polyethylene (PE)										
Loop	• Polyamide (PA)										
2.6	<u>Medical device classification:</u>		I non sterile								
	<u>EU Directive:</u>		93/42/CEE								
	<u>Notified body:</u>		NA								

- ✓ Latex free
- ✓ PVC free

3. Sterilization process if applicable	
	<u>Sterilization process:</u> No sterilization
4. Shelf life	
	3 years
5. Storage conditions	
	<ul style="list-style-type: none"> <li>✓ Keep away from heat</li> <li>✓ Keep in a dry place</li> </ul>

**6. Instructions for use**

See instruction for use of the product used

