

<b>Product Specification</b> <b>8821EBULK</b>		<b>Page 1 of 4</b>
<b>Document Number</b>		<b>QFM196</b>
<b>Revision</b>	<b>4</b>	<b>Date of issue</b> <b>April 2022</b>

## Product Specification

<b>Product Code</b>	<b>8821EBULK</b>
<b>Description</b>	<b>WHITE PIBA FOR ENFIT TIPS FOR BOTTLE NECKS ID 18-22MM (supplied in bulk)</b>

**Note: product code is specifically for BBraun relating to their Material Code BC010176B**

<b>Contract Manufacturer</b>	Plastic Parts Medical Ltd Unit 6b Thorpe Drive Banbury Oxon OX16 4UZ	A051
<b>Legal manufacturer/ CE mark holder</b>	Miktell Ltd, Aston Court, Kingsmead Business Park, Frederick Place, High Wycombe HP11 1JU UK	
<b>EC Rep</b>	Emergo Europe, Prinsessegracht 20 2514AP The Hague The Netherlands	
<b>EC Importer</b>	B.Braun Melsungen AG 34209 Melsungen Germany www.bbraun.com	

## Product Specification

Classification	Class 1 medical device
Material	UL814 PE
Colour	White
SKU	Bag of 1000
MSC part number	40558
Method of sterility	Supplied non-sterile
Shelf Life	5 years from manufacture

## References and norms

	<b>Reference</b>
To fit internal bottle neck dimensions 18-22mm.	
For use with Enfit syringe tips	ISO80369-3
Material Specification	UL814 General information sheet
Material Test Report	UL814_EC Test Report
Biological Evaluation Report to ISO 10993-1:2009	Miktell Ltd – ENFIT Syringe Medicine Bottle Adapter Version 2.0 – 17 September 2021 (author: Patient Guard)

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### Packaging

In accordance with ISO11607

Double bagged, tumble filled, in quantities of 1000.








5 bags packed in double walled carton 500mm\*350mm\*330mm

### Storage and Handling Requirements

No Specific storage or handling conditions

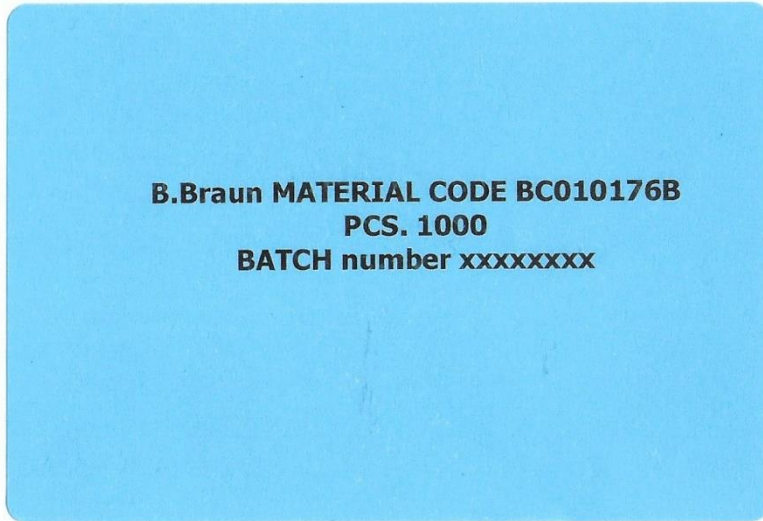
**Labelling** In accordance with ISO 15223-1

Bag of 1000 - Label Reference QFM197 to be placed on outside bag or product

	<b>MIKTELL</b>															
<b>Press In Bottle Adaptor (PIBA) for Enfit tip syringes (White) to fit bottle neck 18-22mm BC010176B</b>																
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; text-align: center;">REF</td> <td style="width: 25%; text-align: center;">8821EBULK</td> <td style="width: 15%; text-align: center;">LOT</td> <td style="width: 15%; text-align: center;">XXXXXXX</td> <td style="width: 15%; text-align: center;">PCS</td> <td style="width: 15%; text-align: center;">1000</td> </tr> <tr> <td style="text-align: center;"></td> <td style="text-align: center;">XXXX-XX</td> <td style="text-align: center;"></td> <td style="text-align: center;">XXXX-XX</td> <td></td> <td style="text-align: center;"><table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;"><b>MD</b></td> </tr> <tr> <td style="font-size: 8px; text-align: center;">Medical Device</td> </tr> </table></td> </tr> </table>	REF	8821EBULK	LOT	XXXXXXX	PCS	1000		XXXX-XX		XXXX-XX		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;"><b>MD</b></td> </tr> <tr> <td style="font-size: 8px; text-align: center;">Medical Device</td> </tr> </table>	<b>MD</b>	Medical Device	Miktell Ltd, Aston Court Kingsmead Business Park, Frederick Place High Wycombe UK HP11 1JU Tel: +44 (0) 1494 616 082 <a href="http://www.miktell.com">www.miktell.com</a>	
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Bag of 1000 – one to be placed on both internal and external bags



Box of 5 bags of 1000 - Label Reference QFM198






**Press In Bottle Adaptor (PIBA)  
for Enfit tip syringes (White)  
to fit bottle neck 18-22mm  
BC010176B**

REF	<b>8821EBULK</b>	LOT	XXXXXX	PCS	5 bags of 1000
	XXXX-XX		XXXX-XX		<b>MD</b> <small>Medical Device</small>

	Miktell Ltd, Aston Court Kingsmead Business Park, Frederick Place High Wycombe UK HP11 1JU Tel: +44 (0) 1494 616 082 <a href="http://www.miktell.com">www.miktell.com</a>	<table border="1" style="margin: auto;"> <tr> <td style="padding: 5px;"><b>EC</b></td> <td style="padding: 5px;"><b>REP</b></td> </tr> </table> EMERGO EUROPE Prinsessegracht 20 2614 AP The Hague The Netherlands	<b>EC</b>	<b>REP</b>
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### Product Drawing

