

PRODUCT SPECIFICATION

Product Code	6800E
Description	PIBA for Enfit tips 17-20mm (Box of 100)

Contract Manufacturer	Micsafe Medical Group 6-722 Oasis Middle Ring Centre No. 1678 Jinshajiang Road Shanghai 200333 China At manufacturing site: Jiangsu Micsafe Medical Technology Co.,Ltd Xituan Industrial Park, Dafeng District, Yancheng City, Jiangsu Province, China	A022
Legal manufacturer/ CE mark holder	Miktell Ltd, Aston Court, Kingsmead Business Park, Frederick Place, High Wycombe HP11 1JU UK	
EC Rep	Emergo Europe, Prinsessegracht 20 2514AP The Hague The Netherlands	

Product Specification

Classification	Class 1 medical device		
Material	UL814 PE		
Colour	Blue		
UDI	05060386541264		
Box of 100	6800E	UDI	35060386541265
Bag of 1000	6800EBULK	UDI	25060386541268
Box of 10,0000	10*6800EBULK	UDI	15060386541261
Method of sterility	Supplied non-sterile		
Shelf Life	5 years from manufacture		

References and norms

	Reference
To fit internal bottle neck dimensions 18-22mm.	
For use with Enfit syringe tips	ISO80369-3
Material Specification	UL814 General information sheet
Colourant	BASF Irgalite® Blue GLO
Material Test Report	UL814_EC Test Report
Biological Evaluation Report to ISO 10993-1:2009	Miktell Ltd – ENFIT Syringe Medicine Bottle Adapter Version 1.0 – 12 September 2018 (author: Patient Guard)

Packaging

6800E	Single bagged, tumble filled, in box of 100.
6800EBULK	Double bagged, tumble filled, in bag of 1000.







Storage and Handling Requirements

No Specific storage or handling conditions




Labelling

In accordance with ISO 15223-1






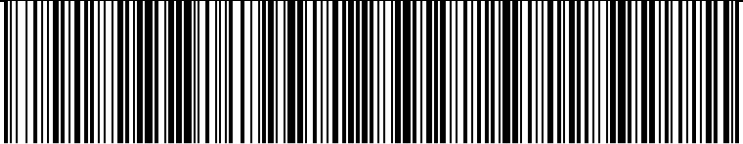
6800E Label Reference QFM148

 MIKTELL		QFM148 Rev D
Press In Bottle Adaptor (PIBA) for Enfit tip syringes (Blue) to fit bottle neck 17-20mm		
REF 6800E	LOT XXXXXXXX	QTY 100
 YYYY-MM	 YYYY-MM	MD Medical Device
 Miktell Ltd, Aston Court Kingsmead Business Park, Frederick Place High Wycombe UK HP11 1JU	EC REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
		
(01) 35060386541265 (17) 010826 (10) 00000000		

6800EBULK Label Reference QFM151

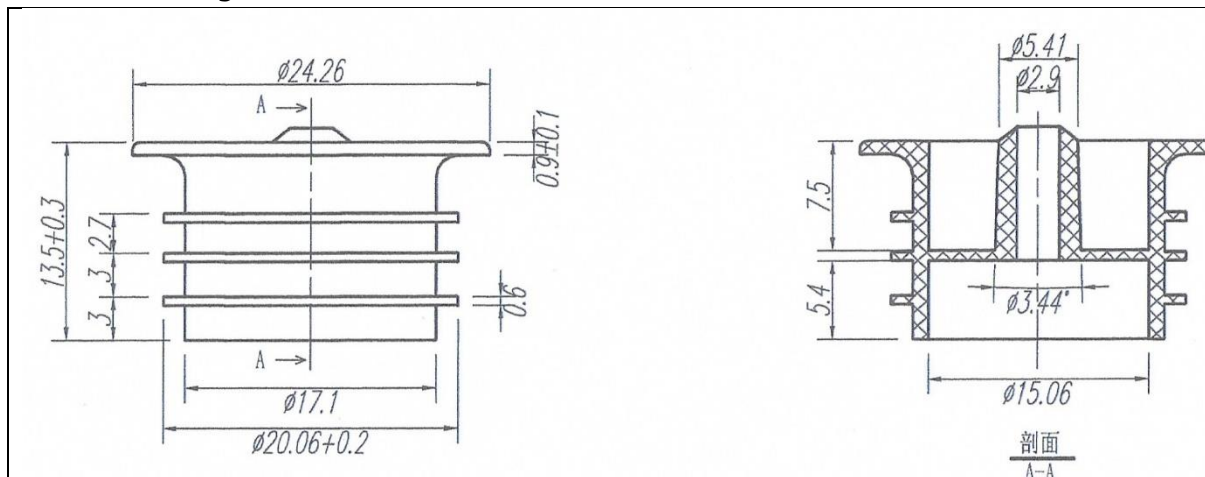
 MIKTELL		QFM151 Rev C
Press In Bottle Adaptor (PIBA) for Enfit tip syringes (Blue) to fit bottle neck 17-20mm		
REF 6800EBULK	LOT XXXXXXXX	QTY 1000
 YYYY-MM	 YYYY-MM	MD Medical Device
 Miktell Ltd, Aston Court Kingsmead Business Park, Frederick Place High Wycombe UK HP11 1JU	EC REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
		
(01) 25060386541268 (17) 010826 (10) 00000000		

6800EBULK box of 10 bags Label Reference QFM174

	MIKTELL		QFM174 Rev A
Press In Bottle Adaptor (PIBA) for Enfit tip syringes (Blue) to fit bottle neck 17- 20mm			
REF	6800EBULK	LOT	XXXXXXXX
		QTY	10 BAGS OF 1000
	YYYY-MM		YYYY-MM
			MD Medical Device
	Miktell Ltd, Aston Court Kingsmead Business Park, Frederick Place High Wycombe UK HP11 1JU	EC REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
 (01) 0506038654151 (17) 20210801 (10) 202608			

Product Drawing

Micsafe drawing ref: JLJ-Micsafe-CP-201



Technical Requirements:

1. Product surface must not have burrs, bubbles, defects or plastic flow defects
2. Product Surface should be clean, no discolouration or foreign matter
3. Rounded corners not marked R0.3

4. In addition to the special dimensioning on the surface of the tolerance, if the size is less than 10mm tolerance is 0.05mm, greater than or equal to 10mm tolerance of 0.1mm