

technical data

Generic Device Group	Applicators			
Product Name	Micro Applicator Tips			
Models	Model	Description	Head Size	Available in:
	921	Regular	2.5mm dia.	Blue, Green, Lavender or Yellow
	922	Fine	2.0mm dia.	
	7502	Autoclavable Tip Handle	N/A	White or Transparent
Image	 921 Regular  REGULAR  922 Fine  FINE  Figure 1: 7502T			
Regulation	Medical Device Regulation (EU) 2017/745			
Classification and Rule	Class I, Rule 5			
Basic UDI-DI	++D838APPLICATORY9			
Intended Use	Disposable applicators used for placement of small controlled amounts of dental materials such as etchants, bonding agents, sealers and cements etc. in limited access areas.			
Indications of use	- For professional dental application only - Non-absorbent fibres - Bendable neck			
Packaging Description	921, 922	Primary	100 pcs/box	
		Secondary	100 boxes/case	
	7502	Primary	1 piece/pack	
		Secondary	100 boxes/case	
Packaging Languages	EN, DE, FR, IT, ES, PT, JA, ZH			
Composition	Component	Device / Accessory Ref.	Material Type	
	Handle	921, 922	Polypropylene (PP)	
	Adhesive		Epoxy resin	
	Fibre head		Nylon (PA/66)	
	Handle	7502T	Polycarbonate (PC)	
		7502W	Polypropylene (PP)	
Traceability	UDI / LOT			
Shelf Life	5 years			
Storage Conditions	Do not store in direct sunlight, store in a cool dry place			

Country of manufacture	China	
Nomenclature	EMDN	Q019006
	GMDN	35697
	UMDNS	10172
Reprocessing	921, 922	Single use only
	7502	Autoclavable to 134°C
Material Safety Data Sheet	N/A	
Manufacturer	Premium Plus International Ltd.	
Manufacturer SRN	TBC	
EU Representative	Premium Plus Poland sp. z o.o.	
EU Representative SRN	TBC	
UK Representative	Premium Plus UK Ltd.	

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