

technical data

Generic Device Group	Applicators				
Product Name	Brush Applicators				
Models	Model	Description	Head Size	Handle Length	Available in:
	7500	Regular	11mm	110mm x 3mm	Blue, Green, Lavender or Yellow
	7510	Fine	7mm	108mm x 3mm	
	7501	Regular	11mm	N/A	
	7511	Fine	7mm	N/A	
	7502	Autoclavable Tip Handle	N/A	143mm x 13mm	White or transparent



Figure 1: 7500 / 7510

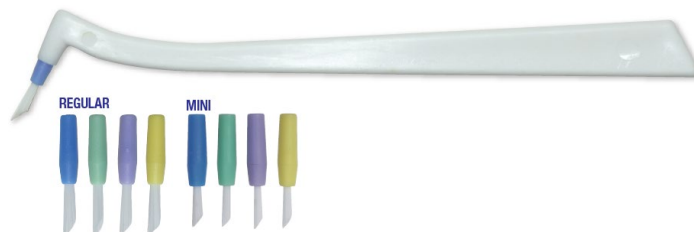


Figure 2: 7501 / 7511 / 7502W

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 - For placement on larger surface areas - Non-absorbent fibres - Bendable neck		
Packaging Description	7500, 7510, 7501, 7511	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 / Material	Component	Device / Accessory Ref.	Material Type
	Handle	7500, 7510, 7501, 7511	Polypropylene (PP)
	Adhesive		Epoxy resin
	Fibre head		Nylon (PA/66)
	Handle	7502T	Polycarbonate (PC)
		7502W	Polypropylene (PP)
Traceability	UDI / LOT		
Shelf Life / Expiry	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	7500, 7510, 7501, 7511	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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