
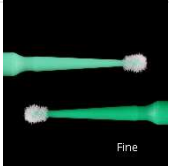

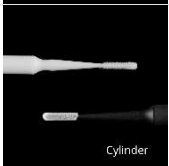

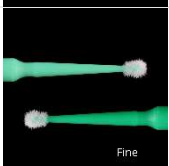



technical data

Generic Device Group	Applicators					
Product Name	Micro Applicators					
Models	Model	Image	Size	Head Size	Handle Length	
	901		Regular	2.5mm dia.	100mm x 3mm	
	902		Fine	2.0mm dia.	100mm x 3mm	
	903		Ultrafine	1.5mm dia.	100mm x 3mm	
	904		Cylinder	1.2mm dia. 5.5mm length	100mm x 3mm	
	9901		Regular	2.5mm dia.	85mm x 2.5mm	
	9902		Fine	2.0mm dia.	85mm x 2.5mm	
	9903		Ultrafine	1.5mm dia.	85mm x 2.5mm	
	Regulation	Medical Device Regulation (EU) 2017/745				
	Classification and Rule	Class I, Rule 5				
Basic UDI-DI	++D838APPLICATORY9					
Intended Use	An Applicator is an invasive device intended for the placement of small amounts of dental materials such as etchants, bonding agents, sealers and cements onto the surface of the tooth. This is a single use device.					
Indications of use	<ul style="list-style-type: none"> - For professional dental application only - Single use only - Non-absorbent fibres - Bendable neck 					

Accessories	Model	Description	For use with
	18-900	Applicator Dispenser Standard	901, 902, 903, 904
	18-9900	Applicator Dispenser Mini	9901, 9902, 9903

Packaging Type	Product Codes	Type	Quantity
 Tube Pack	901T, 902T, 903T, 904T	Primary	4 tubes/box (100 pcs/tube)
		Secondary	20 boxes/case
	9901T, 9902T, 9903T	Primary	100 tubes/ctn (100 pcs/tube)
		Primary	4 tubes/box (100 pcs/tube)
		Secondary	20 boxes/case
		Primary	100 tubes/ctn (100 pcs/tube)
 Dispenser Pack	901D, 902D, 903D, 904D	Primary	4x100 pcs/box
		Secondary	2x20 boxes/case
 Bulk Pack	901B, 902B, 903B, 904B, 9901B, 9902B, 9903B	Primary	1000 pcs/box
		Secondary	20 boxes/case

Packaging Languages	EN, DE, FR, IT, ES, PT, JA, ZH
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Composition	Handle	Polypropylene (PP)
	Adhesive	Epoxy resin
	Fibre head	Polyamide (PA/66)

Traceability	UDI / LOT
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Shelf Life	5 years
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Storage Conditions	Do not store in direct sunlight, store in a cool dry place
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Country of manufacture	China
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Nomenclature	EMDN	Q019006
	GMDN	35697
	UMDNS	10172

Reprocessing	N/A
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Material Safety Data Sheet	N/A
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Manufacturer	Premium Plus International Ltd.
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Manufacturer SRN	HK-MF-000039905
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EU Representative	Premium Plus Poland sp. z o.o.
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EU Representative SRN	PL-AR-000030110
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UK Representative	Premium Plus UK Ltd.
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