


technical data

Generic Device Group	Sterilisation Pouches and Rolls		
Model	Self-Sealing Sterilisation Pouches		
		External (mm)	Internal (mm)
	6000	57 x 90	33 x 57
	6001	57 x 130	33 x 86
	6003	90 x 145	66 x 98
	6005	70 x 230	46 x 183
	6007	90 x 230	66 x 182
	6009	135 x 260	107 x 209
	6011	190 x 330	162 x 280
6015	250 x 380	222 x 325	
Image			
Regulation	Medical Device Regulation (EU) 2017/745		
Classification and Rule	Class 1, Rule 1		
Basic UDI-DI	++D838STPOUCHHT		
Intended Use	Self-sealing sterilisation pouches are intended to be used to enclose medical devices that are to be sterilized by a health care provider via an autoclave (steam sterilisation). Sterilisation pouches maintain the sterility of the enclosed device until used. Sterilisation Pouches are intended for sterilisation of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).		
Indications of use	<ul style="list-style-type: none"> - For professional dental application only - Single use - For steam sterilisation - Internal and external indicators (Blue to Dark Grey) - Maintains sterility of equipment until use 		
Self-Sealing Operation	<ul style="list-style-type: none"> - Place the instrument inside the sterilisation pouch - Remove protective strip form the adhesive at the open end of the pouch - Fold the strip along the perforated edge - Apply pressure firmly along the entire length of the adhesive seal, starting from the centre and working your thumbs outwards to produce a flat seal - Repeat applying pressure two more times - Examine the seal to make sure you it is secure, and no uneven spots or ridges appear 		
Packaging Description	6000, 6001, 6003, 6005, 6007, 6009, 6011	Primary	200 pcs/box
		Secondary	10 boxes/case
	6015	Primary	100 pcs/box
		Secondary	10 boxes/case
Packaging Languages	EN, PL, DE, FR, IT, ES, PT, FI, NO, SV, JA, ZH		

Composition	Film	60µm Polypropylene film
	Paper	70gsm Medical Grade Paper
Traceability	UDI / LOT	
Shelf Life / Expiry	Prior to sterilisation	3 years
	Post sterilisation	6 months
Storage Conditions	Do not store in direct sunlight, store in a cool dry place	
Country of Manufacture	China	
Nomenclature	EMDN	S01010101
	GMDN	13735
	UMDNS	13735
Material Safety Data Sheet	N/A	
Manufacturer	Premium Plus International Ltd.	
Manufacturer SRN	HK-MF-000039905	
EU Representative	Premium Plus Poland sp. z o.o	
EU Representative SRN	PL-AR-000030110	
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