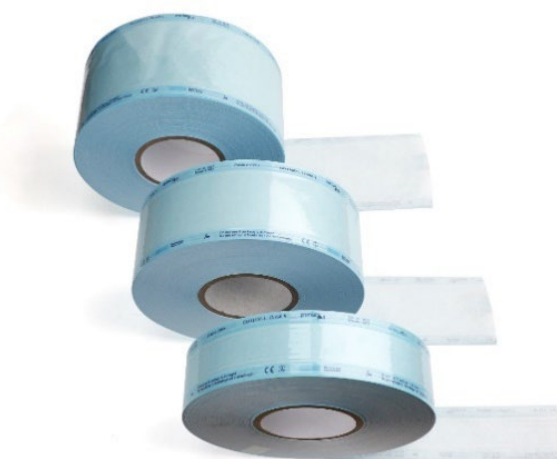


# technical data

<b>Generic Device Group</b>	Sterilisation Pouches and Rolls		
<b>Model</b>	Sterilisation Rolls		
		External (width [mm] x length [m])	Internal (width [mm] x length [m])
	6052	50 x 200	30 x 200
	6053	75 x 200	51 x 200
	6054	100 x 200	76 x 200

**Image**



<b>Regulation</b>	Medical Device Regulation (EU) 2017/745		
<b>Classification and Rule</b>	Class 1, Rule 1		
<b>Basic UDI-DI</b>	++D838STPOUCHHT		
<b>Intended Use</b>	Sterilisation rolls 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 rolls maintain the sterility of the enclosed device until used. Sterilisation rolls are intended for sterilisation of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).		
<b>Indications of use</b>	<ul style="list-style-type: none"> <li>- For professional dental application only</li> <li>- Single use</li> <li>- For steam sterilisation</li> <li>- External indicators (Blue to Dark Grey)</li> <li>- Maintains sterility of equipment until use</li> </ul>		
<b>Packaging Description</b>	6052, 6053, 6054	Primary	200 m/pack
		Secondary	10 rolls/case
<b>Packaging Languages</b>	EN, PL, DE, FR, IT, ES, PT, FI, NO, SV, JA, ZH		
<b>Composition</b>	Film	60µm Polypropylene film	
	Paper	70gsm Medical Grade Paper	
<b>Traceability</b>	UDI / LOT		
<b>Shelf Life / Expiry</b>	Prior to sterilisation	3 years	
	Post sterilisation	6 months	
<b>Storage Conditions</b>	Do not store in direct sunlight, store in a cool dry place		
<b>Country of Manufacture</b>	China		

<b>Nomenclature</b>	EMDN	S01010101
	GMDN	13735
	UMDNS	13735
<b>Material Safety Data Sheet</b>	N/A	
<b>Manufacturer</b>	Premium Plus International Ltd.	
<b>Manufacturer SRN</b>	HK-MF-000039905	
<b>EU Representative</b>	Premium Plus Poland sp. z o.o	
<b>EU Representative SRN</b>	PL-AR-000030110	
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