

technical data

Generic Device Group	Dental LED Curing Lights	
Model	C01-C	LED Curing Light with Fibre Optic Light Guide, Classic
	C01-S	LED Curing Light with Fibre Optic Light Guide, Super Power
	C01-D	LED Curing Light with Fibre Optic Light Guide, Dual Range
	C01-M	LED Curing Light with Fibre Optic Light Guide, Mini

**Refer to catalogue for full product specifications and images*

Image



Figure 1: C01-C Pink

Colors	<table border="1"> <tr> <td>BLUE</td> <td>L.GREEN</td> <td>L.LAVENDER</td> <td>ORANGE</td> <td>WHITE</td> </tr> <tr> <td>L.BLUE</td> <td>LIME</td> <td>PINK</td> <td>YELLOW</td> <td>BLACK</td> </tr> </table>	BLUE	L.GREEN	L.LAVENDER	ORANGE	WHITE	L.BLUE	LIME	PINK	YELLOW	BLACK										
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Regulation	Medical Device Regulation (EU) 2017/745																				
Classification and Rule	Class I, Rule 13																				
Basic UDI-DI	++D838CURINGLIGHTWN																				
Intended Use	Dental LED Curing Lights are intended to be used to activate the polymerization of a dental resin-based material in the oral cavity. This is an active, reusable device.																				
	<ul style="list-style-type: none"> - For professional dental application only - Refer to instructions for use - Latex free (Does not contain natural rubber latex) 																				
Other	<p>Replacement parts</p> <table border="1"> <tr> <td>C01-[X]-1</td> <td>Fibre Optic Light Guide</td> </tr> <tr> <td>C01/2-1, C01/2-M-1</td> <td>Rechargeable Lithium-ion Battery</td> </tr> <tr> <td>C01-[X]-4</td> <td>Charging Base</td> </tr> <tr> <td>C-S3</td> <td>Power Adaptor 100-240V</td> </tr> <tr> <td>C01-S/D-4</td> <td>Autoclavable Tack Rings</td> </tr> </table> <p><i>*[X] = Model ie. C, S, D or M</i></p>	C01-[X]-1	Fibre Optic Light Guide	C01/2-1, C01/2-M-1	Rechargeable Lithium-ion Battery	C01-[X]-4	Charging Base	C-S3	Power Adaptor 100-240V	C01-S/D-4	Autoclavable Tack Rings										
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Packaging Description	C01-C/S/D	Primary	1set/box
		Secondary	10boxes/case
	C01-M	Primary	1set/box
		Secondary	20boxes/case
Packaging Languages	EN, DE, FR, IT, ES, PT, JA, ZH		
Composition	Handpiece/ Charging Base	Polycarbonate (PC)	
	Fibre optic light guides	Glass/ Copper	
	Light Shield	Polycarbonate / Silicone	
	Barrier Sleeves	Low Density Polyethylene (LDPE)	
Traceability	UDI / LOT/ Serial Number		
Warranty	24 Months		
Storage Conditions	- Do not store in direct sunlight, store in a cool dry place		
	- Temperature: -10°C ~ 55°C		
	- Relative humidity: 10% ~ 95%		
	- Atmospheric pressure: 50kPa ~106kPa		
Country of Manufacture	China		
Nomenclature	EMDN	Q01010199	
	GMDN	35775	
	UMDNS	16386	
Reprocessing	Refer to Instructions for Use		
Material Safety Data Sheet	Batteries (NCM18650, NCM14500)		
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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