

CURING LIGHT MODEL X



Conformity / Regulatory Information

Generic Device Group	Dental LED Curing Lights	
Model	C01-X LED Curing Light with Fibre Optic Light Guide, model X	
Regulation	Medical Device Regulation (EU) 2017/745	
Classification and Rule	Class I, Rule 13	
Basic UDI-DI	++D125CURINGLIGHTSAR	
Nomenclature	EMDN	Q01010199
	GMDN	35775
	UMDNS	16386
Intended Use	Dental LED Curing Lights are intended to be used to activate the polymerisation of a dental materials in the oral cavity. This is an active, reusable device.	
Indications of use	- For professional dental application only - Refer to instructions for use - Light wavelength 390~430 nm & 440~480 nm	
Other	MODES	
	TURBO	2,000 mW/cm ² for 4 seconds±10%
	FULL	1,200 mW/cm ² for 10 seconds±10%
	RAMP	20 seconds:
		0-5 seconds from 0-1,200 mW/cm ² ±10%
		5-20 seconds 1,200 mW/cm ² ±10%
	SOFT CURE	20 seconds:
		0-5 seconds from 0-900 mW/cm ² ±10%
		5-20 seconds 900 mW/cm ² ±10%
	Replacement parts	
	C01-X-1	11 mm Fibre Optic Light Guide
	C01-2	Protective Light Shield
	C01-4	Autoclavable Tack Rings (6 pcs)
	123M	Disposable Curing Light Sleeves (500 pcs)
	C01-X-LH	Handpiece Lower Half including battery
	USB Type-C plug cord	

	Battery specifications		
	Nominal voltage	3.6 V	
	Capacity	2000 mAh	
	Weight	34.5 g	
	Power output	5V/1A	
Product Specification			
Colours	Available in: light green, light lavender, light blue, blue, pink, white, black		
Dimensions	Weight	173 g	
	Length	265 mm	
Packaging Description	Primary	1set/box	
	Secondary	10boxes/case	
Packaging Languages	EN, PL, DE, FR, IT, ES, PT, FI, NO, SV, DA, RO, CS, EL, HU, LV, LT, SK, JA, ZH		
Composition	Handpiece / Charging Station	Polycarbonate (PC)	
	Fibre Optic Light Guide	Glass	
	Protective Light Shield	Polycarbonate (PC)	
	Autoclavable Tack Rings	Silicone	
	Curing Light Sleeves	Low Density Polyethylene (LDPE)	
Traceability	UDI / LOT / Serial Number		
Storage Conditions	- Do not store in direct sunlight, store in a cool dry place - Temperature: -10 ~ 55°C - Relative humidity: 10% ~ 95% - Atmospheric pressure: 70kPa ~ 106kPa		
Reprocessing	Refer to Instructions for Use		
Manufacturer Information			
Manufacturer	Premium Plus (Dongguan) Ltd.	Manufacturer SRN	CN-MF-000038259
EU Representative	Premium Plus Poland sp. z o.o.	EU Representative SRN	PL-AR-000030110
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