

CURING LIGHT MODEL X



Conformity / Regulatory Information

Generic Device Group	Dental LED Curing Lights	
Model	C02-X LED Curing Light with Direct Light Source Head, 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	2,500 mW/cm ² for 3 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	
	C02-X-1	10 mm Direct Light Source Head
	C02-2	Protective Light Shield
	C02-3	Heat Protective Rings (6 pcs)
	C02-4	Autoclavable Tack Rings (6 pcs)
	125	Disposable Curing Light Sleeves (500 pcs)
	C02-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	139 g
	Length	255 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)
	Direct Light Source Head	Glass/ Stainless steel
	Protective Light Shield	Polycarbonate (PC)
	Heat Protective Rings	Silicone
	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

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