

# technical data

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|-----------------------------|--------------------------|
| <b>Generic Device Group</b> | Dental LED Curing Lights |
| <b>Model</b>                | C03-B                    |

Image



|                                |                                                                                                                                                                            |                                                                                                                                          |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Regulation</b>              | Medical Device Regulation (EU) 2017/745                                                                                                                                    |                                                                                                                                          |
| <b>Classification and Rule</b> | Class I, Rule 13                                                                                                                                                           |                                                                                                                                          |
| <b>Basic UDI-DI</b>            | ++D125CURINGLIGHTSAR                                                                                                                                                       |                                                                                                                                          |
| <b>Intended Use</b>            | 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.   |                                                                                                                                          |
| <b>Indications of use</b>      | <ul style="list-style-type: none"> <li>- For professional dental application only</li> <li>- Refer to instruction for use</li> <li>- Light wavelength 385~515nm</li> </ul> |                                                                                                                                          |
|                                | <b>MODES:</b>                                                                                                                                                              |                                                                                                                                          |
|                                | HIGH                                                                                                                                                                       | 2,500 mW/cm <sup>2</sup> for 1, 3 or 5 seconds                                                                                           |
|                                | NORMAL                                                                                                                                                                     | 1,200 mW/cm <sup>2</sup> for 5, 10, 15 or 20 seconds                                                                                     |
|                                | ORTHO                                                                                                                                                                      | 2,500 mW/cm <sup>2</sup> for 5 x 3 seconds with 1s interval<br><b>OR</b><br>2,500 mW/cm <sup>2</sup> for 10 x 3 seconds with 1s interval |
| <b>Package Contents</b>        | RAMP                                                                                                                                                                       | 1st five seconds from 0-1,200 mW/cm <sup>2</sup> ,<br>next 5, 10, 15 or 20 seconds 1,000-1,200 mW/cm <sup>2</sup>                        |
|                                | <b>CODE</b>                                                                                                                                                                | <b>DESCRIPTION</b>                                                                                                                       |
|                                | C03-B                                                                                                                                                                      | Curing Light Handpiece with Charging Station                                                                                             |
|                                | C03-B-1                                                                                                                                                                    | 10mm Direct Light Source Head                                                                                                            |
|                                | C03-B-2                                                                                                                                                                    | Protective Light Shield                                                                                                                  |
|                                | 125SS                                                                                                                                                                      | Disposable Curing Light Sleeves Short                                                                                                    |
| <b>Other</b>                   | <b>Replacement parts</b>                                                                                                                                                   |                                                                                                                                          |
|                                | C03-B-1                                                                                                                                                                    | Direct Light Source Head                                                                                                                 |

|                                   |                                                                                                                                                                                                                                           |                         |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
|                                   | C03-B-2                                                                                                                                                                                                                                   | Protective Light Shield |
|                                   | C03-B-3                                                                                                                                                                                                                                   | Power Adaptor           |
|                                   | <b>Battery specifications</b>                                                                                                                                                                                                             |                         |
|                                   | Nominal voltage                                                                                                                                                                                                                           | 3.7V                    |
|                                   | Capacity                                                                                                                                                                                                                                  | 1900mAh                 |
|                                   | Weight                                                                                                                                                                                                                                    | 37g                     |
|                                   | Power output                                                                                                                                                                                                                              | 5V/1A                   |
| <b>Packaging Description</b>      | Primary                                                                                                                                                                                                                                   | 1set/box                |
|                                   | Secondary                                                                                                                                                                                                                                 | 10boxes/case            |
| <b>Packaging Languages</b>        | EN, PL, DE, FR, IT, ES, PT, FI, NO, SV, DA, RO, CS, EL, HU, LV, LT, SK, JA, ZH                                                                                                                                                            |                         |
| <b>Composition</b>                | Handpiece/ Charging Station                                                                                                                                                                                                               | ABS+PC                  |
|                                   | Direct Light Source Head                                                                                                                                                                                                                  | Aluminium alloy         |
|                                   | Protective Light Shield                                                                                                                                                                                                                   | PS                      |
|                                   | Curing Light Sleeves                                                                                                                                                                                                                      | PE                      |
| <b>Traceability</b>               | UDI / LOT / Serial Number                                                                                                                                                                                                                 |                         |
| <b>Warranty</b>                   | 12 Months                                                                                                                                                                                                                                 |                         |
| <b>Storage Conditions</b>         | <ul style="list-style-type: none"> <li>- Do not store in direct sunlight, store in a cool dry place</li> <li>- Temperature: -20 ~ 55°C</li> <li>- Relative humidity: 10% ~ 93%</li> <li>- Atmospheric pressure: 70kPa ~ 106kPa</li> </ul> |                         |
| <b>Country of Manufacture</b>     | China                                                                                                                                                                                                                                     |                         |
| <b>Nomenclature</b>               | EMDN                                                                                                                                                                                                                                      | Q01010199               |
|                                   | GMDN                                                                                                                                                                                                                                      | 35775                   |
|                                   | UMDNS                                                                                                                                                                                                                                     | 16386                   |
| <b>Reprocessing</b>               | Refer to Instruction for Use                                                                                                                                                                                                              |                         |
| <b>Material Safety Data Sheet</b> | Batteries (MSDS-18500- 1900mAh)                                                                                                                                                                                                           |                         |
| <b>Manufacturer</b>               | Premium Plus (Dongguan) Ltd.                                                                                                                                                                                                              |                         |
| <b>Manufacturer SRN</b>           | CN-MF-000038259                                                                                                                                                                                                                           |                         |
| <b>EU Representative</b>          | Premium Plus Poland sp. z o.o.                                                                                                                                                                                                            |                         |
| <b>EU Representative SRN</b>      | PL-AR-000030110                                                                                                                                                                                                                           |                         |
| <b>UK Representative</b>          | Premium Plus UK Ltd.                                                                                                                                                                                                                      |                         |

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