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Precision made in Germany

# Product description

| | |
|---|---|
| **Product** | **OcuLED Single-use LED Light Source** |
| **Article** | **OcuLED** |
| **Remarks** | |

| | |
|---|---|
| GMDN-Code | 32079: Ophthalmic light source |
| UMDNS-Code | 12340: Light Sources<br>12345: Light Sources, Fiberoptic |
| PN-Code CA | 86MPA: Endoilluminator |

| **Revision 2** | | |
|---|---|---|
| **Drafted by** | **Reviewed by** | **Released by** |
| Stephanie Haas, QM/RA | Dr. Anaid Shahbazian, QM/RA | Matthias Welke, Head of QM/RA |
| Date/Signature<br>Stephanie Haas<br>14. JAN. 2015 | Date/Signature<br>Anaid Shahbazian<br>14. JAN. 2015 | Date/Signature<br>Matthias Welke<br>14. JAN. 2015 |

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**Product description**

Single-use LED light sources are used for endoillumination to illuminate the eye during vitreoretinal surgery allowing the surgeon to see intraocular details and lesions in the posterior segment of the eye.

The pen-like instruments are made of a plastic handpiece with a with a fiber optic needle. The optical fiber is made of PMMA, the tube is made of stainless steel.

The light sources are connected either to the Megatron S3/S4 system or to an external power supply.

**Product variants**

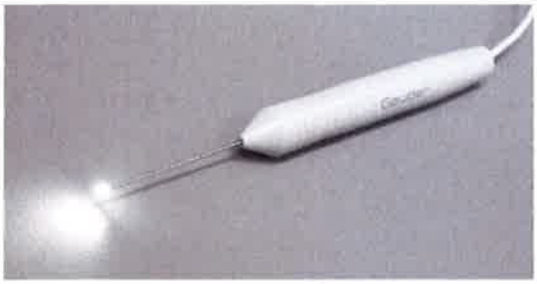
| Article No. G- | Description |
|---|---|
| 26401 | OcuLED single-use LED light source, coolwhite, spot, diameter 20 gauge / 0.9 mm, sterile |
| 26402 | OcuLED single-use LED light source, neutralwhite, spot, diameter 20 gauge / 0.9 mm, sterile |
| 26403 | OcuLED single-use LED light source, coolwhite, wide angle, diameter 20 gauge / 0.9 mm, sterile |
| 26404 | OcuLED single-use LED light source, neutralwhite, wide angle, diameter 20 gauge / 0.9 mm, sterile |
| 26405 | OcuLED single-use LED light source, coolwhite, wide angle, shielded, diameter 20 gauge / 0.9 mm, sterile |
| 26406 | OcuLED single-use LED light source, neutralwhite, wide angle, shielded, diameter 20 gauge / 0.9 mm, sterile |
| 26432 | OcuLED single-use LED light source, neutralwhite, spot, diameter 23 gauge / 0.64 mm, sterile |
| 26433 | OcuLED single-use LED light source, coolwhite, wide angle, diameter 23 gauge / 0.64 mm, sterile |
| 26434 | OcuLED single-use LED light source, neutralwhite, wide angle, diameter 23 gauge / 0.64 mm, sterile |
| 26435 | OcuLED single-use LED light source, coolwhite, wide angle, shielded, diameter 23 gauge / 0.64 mm, sterile |
| 26436 | OcuLED single-use LED light source, neutralwhite, wide angle, shielded, diameter 23 gauge / 0.64 mm, sterile |

**Accessories**

| Article No. G- | Description |
|---|---|
| 26400 | OcuLED Power Source, incl. power supply adapter for Europe |

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**Pictures**



OcuLED light source

**Production plants and Marketing authorisation holder (MAH)**

| Article No. G- | Production plant | MAH |
|---|---|---|
| 26401, 26402, 26403, 26404, 26405, 26406, 26432, 26433, 26434, 26435, 26436 | Geuder AG<br>Hertzstr. 4<br>69126 Heidelberg<br>Germany<br><br>Sterimed Tec AG<br>Hafnerwisentr. 2<br>9442 Berneck<br>Switzerland | Geuder AG<br>Hertzstr. 4<br>69126 Heidelberg<br>Germany |
| 26400 | Geuder AG<br>Hertzstr. 4<br>69126 Heidelberg<br>Germany | |

**Material in contact with the patient**

| Component | Material |
|---|---|
| Cannula | Stainless steel 1.4306 |
| Fiber optic | PMMA |

**Sterilization**

| | |
|---|---|
| Sterilization Method | Gamma sterilization |
| Sterilization plant | Leoni Studer Hard AG<br>4658 Däniken<br>Switzerland |
| Shelf life | Five years |