



Documentation Review

No. 200724.IMGCD72

Holder: **Ingenious Medical GmbH**
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Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: LED LIGHT SOURCES & LIGHT GUIDES WITH ADAPTERS
Intended Purpose: Responsible to produce illumination and enlighten cavities in the patient body

Model(s): *(see the following annex)*

Classification: Class I (Not Sterile according to the Manufacturer's declaration - therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

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Approver
ECM Service Director
Luca Redonni



Expiry date 23 July 2025

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Annex I

No. 200724.IMGCD72

Model(s):

- a. SPECTRA 300 LED LIGHT SOURCE
- b. EPSILON 300 LED LIGHT SOURCE
- c. ECO LED light source
- d. Light Guides
- e. Fitting adapters

