



Documentation Review

No. 200724.IMGCD71

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: CAMERA CONTROLLERS & CAMERA HEADS
Intended Purpose: Capture and transmit an image to the medical display

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

Date of issue 24 July 2020

Approver
ECM Service Director
Luca Redonni



Expiry date 23 July 2025

Technical Expert
Amanda Payne



Annex I

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Model(s):

- a. URSAE Compact Portable Camera System
- b. EPSILON Vision I Camera Controller and Camera Head
- c. SPECTRA 4K Camera Controller and Camera Head
- d. SPECTRA Vision III Camera Controller and Camera Head
- e. EPSILON Vision III Camera Controller and Camera Head
- f. Zoom Couplers

