

Certificate of Compliance



No. 1N160905.SSPTC19

Technical Construction File no. LZ16082302MDD

Certificate's
Holder:

Wuhan Darppon Medical
Technology Co., Ltd
Room 2107, Building 2, Optical Valley Headquarters
International, Optical Valley Avenue, Wuhan City, China

Certification ECM
Mark:



Product:
Model(s):

Medical Endoscope Camera System
(see the following annex I)

Verification to:

Standard:
EN ISO 14971:2012, EN 60601-1:2006/A1:2013,
EN 60601-1-2:2007/AC:2010,
EN 60601-2-18:1996/A1:2000,
EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009,
EN ISO 10993-10:2010, EN 980:2008

related to CE Directive(s):
93/42/EEC amended by 2007/47/EC (Medical
Devices) and subsequent modifications and integrations
ANNEX VII

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the **CE** Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

Date of issue 05 September 2021

Expiry date 04 September 2026

Chief Manager
Tim Mahan

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Ente Certificazione Macchine Srl

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Annex I



No. 1N160905.SSPTC19

Technical Construction File no. LZ1 6082302MDD

Model(s): Medical Endoscope Camera,
Medical Full Hd Endoscopy Camera,
Medical Led Cold Light Source, Medical Monitor,
Endoscopy Remote Service System, Gas Insufflator,
Irrigation Pump, Endoscopy Pump,
Laparoscopy Instruments (5*330mm, 10*330mm),
Laparoscopy Instruments With Electrode, Rigid Endoscopes



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