

CE Declaration of conformity

We, PROMEPLA, 9 avenue Albert II – 98000 MONACO, declare under our full responsibility that the medical devices:

Pipes and accessories for endoscopy
(Cf Product list)

fulfil the dispositions of the Council Medical Device European directive 93/42/EEC of 14 June 1993 and to its transposition into the applicable Part V Book II of the French Public Health Code.

Furthermore, we declare that these devices, in the product list attached, are latex free.

The conformity of these products is based on:

- the technical file (CE marking file) established in accordance with point 3 of Annex VII of the Medical Device Directive 93/42/EEC.
- The CE Conformity Certificate number 10063 Rev 3 following annex V point 3 of the Medical Device Directive 93/42/CEE (Approval of the Production Quality Assurance System), delivered by the LNE/G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15, France, registered number 0459.

Monaco, September 2nd, 2014



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Product List

Référence Promepla	Référence Olympus	Désignation	Classe
ONG04199ST199	WA95005A	Insufflation tubing with filter	Ila
ONG04299ST199	WA95007A	Smoke evacuation tubing	Ila

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