PROMEPLA
Société Anonyme Monégasque au capital de 588.420 €
S.S.E.E. 4669 B0 1526 – R.C.I. 69 S 1239
N° individuel d'identification FR29000009059

CE Declaration of conformity

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

Medical Devices for Dentistry, Endoscopy, Gynecology, Ophthalmology, Perfusion, Transfusion and Dialysis.
Sterile or no Sterile, Single Use or Reusable, Not-Implantable Medical Devices.
Family Perfusion – Transfusion – Dialysis

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

The conformity of these products is based on:

- The technical file (*marking file #FOR130-0-P-PTD*) established in accordance with point 3 of Annex VII of the Medical Device Directive 93/42/EEC.

- The CE Conformity Certificate number n°10061 rev.8 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, January 18, 2019

Tahiana Rasolofoniaina

Regulatory Affairs Specialist

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Perfusion / Transfusion / Dialysis – Products List

PROMEPLA Reference	PROMETHEUS Reference	Designation of the product	Class.
QGG01199ST189	PDF102	RUSSELL PNEUMOFIX	IIa
QGG01299ST189	PDF109	RUSSELL PNEUMOFIX 8cm	IIa
OBG05699ST189	PDF103	PROMETHEUS PIN	IIa

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