

Date: 4th March, 2019

EC Declaration of Conformity

- i. We declare that our product, as listed below, comply with the requirement of Medical Device Directive (MDD/93/42/EEC) +Amendment 2007/47/EC, Annex II.
Name of Product : Digital Video Colposcope
Model No. : COLpro 222DX-OZview
Classification : Class I
- ii. Promis Medical (Australia) Pty Ltd, Undertakes to manufacture the products as per National /International Standards as specified in its quality system and as per the requirements of Medical Device Directive (MDD).
- iii. Company or its authorized representative shall fulfill the obligations imposed by the MDD & ensures & declares that the company's products shall meet all provisions of the directive as applicable.
- iv. Company undertakes to keep up-to-date a systematic procedure to review experience gained during post production phase and implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.



Management Representative
S. Maithani
Promis Medical (Australia) Pty Ltd.

Promis Medical (Australia) Pty Ltd

46/11-13 Brookhollow Ave, Baulkham Hills, NSW 2153, Australia
Postal Add: P O BOX 6439, Baulkham Hills, NSW 2153, Australia
Admin & Logistics Add: 5/25 Stoddart Road, Prospect, NSW 2148, Australia
E-mail: info@promis-medical.com.au, Tel/Fax: +61 2 9896 1978
Website: www.promis-medical.com.au

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