

Date: 4th October, 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.



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