

Dated: 14<sup>th</sup> March 2011

**DECLARATION OF CONFORMITY**  
**Electromagnetic Compatibility**

We, **Promis Medical (Australia) Pty. Ltd.** declare that the product :

**Name of the Product:**

**DIGITAL VIDEO COLPOSCOPE**

**Model:** COLpro222DX-OZview including standard accessories power cable, BNC cable, SVHS cable, patient data management software kit (Promis Capture Card, Colposcopy Software CD, Foot Pedal, USB Cable, Dongle Key, Remote)

Is in conformity with the provisions of the **Electro Magnetic Compatibility Directive** when installed and operated according to the supplied instructions.

For the evaluation of the compliance with the Directive, standard IEC 60601-1-2:2007 was applied.

The tests relevant for the said Directive are mentioned in the test report reference document.

Test Report issued by: SAMEER-CEM, Chennai



**Promis Medical (Australia) Pty Ltd**

Level 2, 30/11-13 Brookhollow Avenue, Baulkham Hills, NSW 2153, Australia  
Phone / Fax: +61 2 8850 6918, E-mail: info@promis-medical.com.au  
PO BOX 6439, Baulkham Hills, NSW 2153, Australia

[www.promis-medical.com.au](http://www.promis-medical.com.au)

**Professional Products for Medical  
Instrumentation & Systems**

- Colposcopy
- Laparoscopy
- Gynaecology
- Urology
- ENT
- Arthroscopy
- Others

**EU-DECLARATION OF CONFORMITY**  
**According to Directive 2011/65/EU (RoHS)**

Name & address of the manufacturer : **Promis Medical (Australia) Pty Ltd**  
**Unit 46 / 11-13 Brookhollow Avenue,**  
**Baulkham Hills, NSW 2153, Australia**

We declare under our sole responsibility that the article listed in the annex to this declaration are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. In particular, we declare that in homogeneous materials the following limits are not exceeded, or at least within the limits, as described in the exceptions in annex III and IV.

Substance	Limit (Weight-%)
Lead (Pb)	0,1%
Mercury (Hg)	0,1%
Cadmium (Cd)	0.01%
Hexavalent Chromium (Cr6+)	0,1%
Polybrominated biphenyls (PBB)	0,1%
Polybrominated diphenyl ethers (PBDE)	0,1%

In this case, the exceptions are listed in attached product list.

**Signed for and on behalf of** :- **Promis Medical (Australia) Pty Ltd**

**Place and date of issue** :- **Sydney, 2.7.2014**



**Promis Medical (Australia) Pty Ltd**

Unit 46, Level 3, 11-13 Brookhollow Avenue, Baulkham Hills, NSW 2153, Australia  
 Tel/Fax : +61 2 8850 6918 Mb : +61 421 415 650  
 Postal Add: PO Box 6439, Baulkham Hills, NSW 2153, Australia  
 E-mail: info@promis-medical.com.au

**www.promis-medical.com.au**

**Professional Products for Medical Instrumentation & Systems**

- Colposcopy
- Laparoscopy
- Gynaecology
- Urology
- ENT
- Arthroscopy
- Others

## ATTACHMENT

### EU-DECLARATION OF CONFORMITY

According to Directive 2011/65/EU (RoHS)

Article Number	Article Description	Exception (if applicable)
COLpro222DX-OZview COLpro777-FullHD COLpro222DX-OZview-HD	Digital Video Colposcope	none



### Promis Medical (Australia) Pty Ltd

Unit 46, Level 3, 11-13 Brookhollow Avenue, Baulkham Hills, NSW 2153, Australia  
 Tel/Fax : +61 2 8850 6918 Mb : +61 421 415 650  
 Postal Add: PO Box 6439, Baulkham Hills, NSW 2153, Australia  
 E-mail: info@promis-medical.com.au

[www.promis-medical.com.au](http://www.promis-medical.com.au)

### Professional Products for Medical Instrumentation & Systems

- Colposcopy
- Laparoscopy
- Gynaecology
- Urology
- ENT
- Arthroscopy
- Others