ECLERIS

EC DECLARATION OF CONFORMITY

We, Ecleris S.R.L., located in Buenos Aires, Argentina, manufacturers of Diagnostic and Therapeutic Medical Devices as detailed hereunder, that are placed in the European market, declare that our products conform and meet the essential requirements set out in Annex I of the Medical Device Directive 93/42 EEC and the revision 2007/47/EC and with UK statutory instrument SI 618 2002, and we have completed all requirement as set up in Annex VII.

Product	Class
ENDODIGI - Image Capturing System	I
MINIVAC - Aspiration System	I
MICROSTAR MICROSCOPE - SERIES OM-100	I
MICROSTAR COLPOSCOPE - SERIES C-100	I
Halolux 150 Duo - Light Source	I
XENOLUX - Light Source	I
PROCAM - CCD Camera	I
PHONOLAB - Voice Laboratory	I
ENDOSCOPES (flexible nasopharyngoscopes, laryngoscopes, otoscopes and sinuscopes)	I
EVERLUX - Light Source	I

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Medes Limited from, 5 Beaumont Gate, Shenley Hill, Radlett Hearts, London WD7 7AR England, to act as our Authorized Representative in the European Community.

On behalf of Ecleris S.R.L

Signature:

Full Name: Marcos Ledesma

Position: Director

Date: 02/03/2016

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