APPLE BioMedical Inc.

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EU Declaration of Conformity

Product: Type Designation/Trademark: Classification: Conformity Assessment Route:

Video Otoscope MS101 MDSCOPE Class I 93/42/EEC

APPLE BioMedical Inc., declares under its sole responsibility that our product to which this declaration relates is in conformity with the provisions of the European Council Directive 93/42/EEC (MDD), as amended by Directive 2007/47/EC concerning medical devices.

This product has been classified as Class I and with the following standards :

93/42/EEC EN 980:2008 EN 60601-1:2005 EN 60601-1-2:2007 ISO 14971:2007 ISO 13485:2003

European Representative : **Medical Device Safety Service GmbH** Schiffgraben 41, 30175 Hannover Germany



Charles K. Huang / General Manager Jan. 05, 2012