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Tel : 886-2-2999-5505 / Fax : 886-2999-6605

EU Declaration of Conformity

Product: Video Otoscope with Accessories

Type Designation/Trademark: MS101 MDSCOPE

(including MS101-002T, MS101-022T, MS101-012T,
MS101-013T, MS101-014T, MS101-015, MS101-019)

Classification: Class I

Conformity Assessment Route: 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)and Directive 2011/65/EU, as amended by Directive 2007/47/EC concerning medical devices.

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

ISO 10993-1:2009

EN 60601-1:2005

EN ISO 14971:2009

ISO 15223-1:2012

EN 60601-1-2:2007

EN ISO 13485:2012

European Representative :

Medical Device Safety Service GmbH

Schiffgraben 41, 30175 Hannover

Germany

A handwritten signature in blue ink, appearing to read "Charles K. Huang", is written over a horizontal dashed line.

Charles K. Huang / General Manager

Mar. 25, 2017