



STURDY INDUSTRIAL CO., LTD.

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DECLARATION OF CONFORMITY

For the following equipment:

Product Name: Handpiece Cleaner

Designation: LC-01 series

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC as Amended by 2007/47/EC** with the compliance of conformity assessment in Annex VII .



For the evaluation regarding the **Class I** product safety aspects, the following **harmonised standards** are applied:

EN 60601-1 : 2006 + AC : 2010,

EN 60601-1-2:2007,

EN 980:2008,

EN ISO 14971:2007

The following European Authorized Representative is stated to the declaration:

APEX MEDICAL S.L.

Mr. Jon Jauregui

Maximo Aguirre 18, Bis. 8th floor, 48011 Bilbao. Vizcaya. SPAIN

The following person is responsible for the compliance of declaration:

STURDY INDUSTRIAL CO., LTD.

Mr. Wolfgang Huang,

Quality Assurance

Taipei, Taiwan

May 4, 2012

name and position

legally signature

date