STURDY INDUSTRIAL CO., LTD.
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DECLARATION OF CONFORMITY

For the following equipment:

Product Name: Sterilizers/Autoclaves

Designation:

Type B	SA-260MB, SA-300MB, SA-302MB
Type S	SA-230MA-R, SA-260MA-R, SA-300MA-R, SA-300VMA-R
Type N	SA-230M-R, SA-260M-R, SA-300M-R, SA-300VM-R, SA-230FA-R, SA-260FA-R, SA-300FA-R, SA-300VFA-R, SA-202N, SA-232N, SA-252N, SA-300N

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 Article 11.3.a and Annex II excluding section 4 (Module H). The notified body is DNV Product Assurance AS (number – CE 2460).

For the evaluation regarding the **Class IIb, rule 15 of annex IX,** product safety aspects, the following **harmonised standards** are applied:

EN 13060:2014	Small steam sterilizers
EN 61010-1:2010 / IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements
EN 61010-2-040:2015/ IEC 61010-2-040:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
EN 61326-1:2013/ IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements

The following European Authorized Representative is stated to the declaration:

APEX MEDICAL S.L.

Elcano 9, 6 ª planta 48008 Bilbao. Vizcaya SPAIN

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The following person is responsible for the compliance of declaration:

STURDY INDUSTRIAL CO., LTD.

Mr. Wolfgang Huang

Quality Manager

Taipei, Taiwan

Wolfgang Huang

21 May 2021

name and position *legally signature* *date*