

DECLARATION OF CONFORMITY


For the following equipment:

Product Name: Sterilizers/Autoclaves

Designation:

Type others SA-230MA, SA-260MA, SA-300MA, SA-300VMA, SA-230M, SA-260M, SA-300M,
SA-300VM, SA-230FA, SA-260FA, SA-300FA, SA-300VFA, SA-202, SA-230,
SA-232, SA-232V, SA-202X, SA-232X, SA-300E, SA-302E,
SA-252F, SA-300H, SA-300VF, SA-300VL, SA-300VLA

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 –  2460).

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

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
And partially comply with clauses of 10.4, 10.5, 10.15 of EN 13060:2014	Small steam sterilizers: Empty chamber test, Solid load test, Microbiological and chemical test

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



21 May 2021

Name and position

Legally signature

Date