

DECLARATION OF CONFORMITY

For the following equipment:

Product Name: Sterilizers/Autoclaves

Designation:

SAT-450HP, SAT-450HPD, SAT-500HP, SAT-500HPD, SAT-600HP, SAT-600HPD

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 285:2006+A2:2009	Sterilization - Steam sterilizers - Large 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



21 May 2021

Name and position

Legally signature

Date