ReSPR™ TECHNOLOGIES

This product is a CE approved Class 1 Medical Device

CE

CE Marking on product is a Manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

DECLARATION OF CONFORMITY

The Manufacturer **ReSPR Technologies Europe** declares under its own responsibility that the device

Model and Article No.	Denomination	CND Classification	No Technical File
ReSPR 200 EU40309	System for treatment and sanitization of air ducts, surfaces, medical apparatus in general, sanitization of disposable devices for general purpose and specialty, clothing, medical disposable and reusable.	**V07**	**NW990-0001**

CLASSIFICATION I

Satisfies all applicable dispositions and the essential requirements (Annexe 1) of Directive 93/42CEE on Medical Devices, modified by the Directive 2007/47/CE.

The Medical Device is manufactured also in conformity with the following Technical standards:

CEI EN 60601-1 (CEI 62.5) for the applicable points

Moreover ReSPR Technologies Europe is committed to:

- Keep the technical documentation specified at point 3 of Annex VII of Directive 93/42/CEE at the disposal of the Notified Body for a period of five years from the date of manufacture of the product. The aforesaid documentation supports this declaration of conformity;

- Maintain an appropriate system for the monitoring of the device, in the phase successive to that of production, and to apply eventual necessary corrective measures, as prescribed in Annex VII.

It is therefore declared that the above-named device will be put on the market with the Class 1 CE mark, according to the dispositions of Article 17 of Directive 93/42/CEE, modified by the Directive 2007/47/CE.

Date 23 June 2018

Signature of Legal Representative

Certified by:

Member of CISQ Federation RINA ISO 9001:2008 Sistema Qualità Certificato