

This product is a CE approved Class 1 Medical Device



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
<b>ReSPR 5.000</b> EU40426	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.	<b>V07</b>	<b>NW990-0005</b>

### 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 09 June 2018

Signature of Legal Representative

Certified by:

