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CE CONFORMITY OF DECLARATION

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Product Name: **Smoke Evacuator**

Model Name: **Airmax**

Classification : **Class I (Annex IX Rule 1, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)**

Conformity Assessment Route : **Annex VII, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC**

Standards applied : **EN ISO 13485:2012, EN ISO 14971:2012, EN1041:2008, ISO15223-1:2012, EN 60601-1:2006, EN 60601-1-2:2007, MEDDEV 2.7.1/Rev.3, MEDDEV 2.12.1/Rev.8, MEDDEV 2.12.2/Rev.2**

EC Representative : **OBELIS S.A BD. Général Wahis, 53, 1030 Brussels, Belgium**



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