



ETHAFILTER S.R.L.

Via dell'Artigianato 16/18 – 36050 Sovizzo (VI) - Italy
Tel.: 0039 (0) 444 3764022 - <http://www.ethafilter.com>

**COMPRESSED AIR
PURIFICATION UNIT**

TWIN-CON^{med}

FOR MEDICAL USE
in compliance with requirements
“Aer medicalis”
of the
European Pharmacopoeia

**DECLARATION OF CONFORMITY
IN COMPLIANCE WITH THE EUROPEAN
DIRECTIVE
98/37/EC**

We **ETHAFILTER s.r.l.** having place of business in Via dell'Artigianato 16/18 – 36050 Sovizzo (VI) - Italy declare to manufacture machinery which satisfies safety requirements so as not to endanger the health and safety of persons, environment, property and animals in accordance with the following EEC directives:

Ref: Directive 89/392 EEC: we declare that our machinery is excluded from the scope of this directive as such machinery consists of assemblies of static pressure vessels which do not require the effort of persons to move them. These appliances are completely static and autonomous and are without external actuators which could cause a safety hazard to those in the immediate surroundings.

Ref: Directive 89/366 EEC: we declare that the assemblies comply in full to the electromagnetic compatibility directive and can withstand a typical level of disturbance without being effected .

Ref: Directive 91/368 EEC: we declare that our machinery is excluded from the scope of this directive as such machinery consists of assemblies of static pressure vessels which do not require the effort of persons to move them. These appliances are completely static and autonomous and are without external actuators which could cause a safety hazard to those in the immediate surroundings.

Ref: Directive 93/44 EEC: we declare that the assemblies do not require the effort of persons to move them. These appliances are completely static and autonomous and are without external actuators which could cause a safety hazard to those in the immediate surroundings. However, equipment consisting of pressure vessels is certified in compliance with the directive 97/23/EC (Pressure Equipment Directive) by the certifying body ITALCERT (0426). This directive requires:

- Risk Assessment
- Essential Health and Safety Requirements
- Safety Components (static safety relief valves to release pressure in the event pressure exceeds the maximum allowable pressure level for the pressure vessels fitted).
- Use and Maintenance Manual (which describes: installation, intended purpose, hazards, maintenance and waste treatment)
- CE Marking (with certifying body identification number where required).

Ref: Directive 93/68 EEC: we declare that the assemblies do not represent equipment whose major hazard is of an electrical nature.

Ref: Directive 2002/96/EC (WEEE – Waste of Electronic and Electrical Equipment) and Directive 2002/95/EC (RoHS – Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment): we declare with reference to polluting substances related to electronic parts the machinery is free of lead, mercury, cadmium, chrome 6 and prohibited flame retardants .

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DATA SHEET

GAS:	compressed air (oil free or not)
DUTY:	continuous 24/24 hours, 800 hours max. between every inspection interval.
INLET AIR PRESSURE:	from 8,5 to 10 bar(g)
COMPRESSED AIR INLET TEMPERATURE:	+ 40°C max.
DEW POINT OUTLET:	- 46° (@ atmospheric pressure)
MOISTURE CONTENTS AT THE INLET:	2.3 g. H ₂ O/m ³ max.
OIL CONTENTS AT THE INLET:	5 mg/m ³ max.
CO CONTENTS AT THE INLET:	50 ppm _v max.
DESIGN PRESSURE OF COLUMNS (PS):	15 bar
DESIGN TEMPERATURE OF COLUMNS (TS):	+ 10 / +60 °C
CODE OF CONSTRUCTION FOR PRESSURE VESSELS:	as per 97/23/EC (PED)
DRYER ASSEMBLY CERTIFICATION:	as per 97/23/EC (PED)
AUXILIARY SUPPLY VOLTAGE:	220-1-50
MAXIMUM Watt CONSUPTION:	25
INSTALLATION:	indoor
AMBIENT TEMPERATURE:	from +5 °C to +35 °C
UNIT WEIGHT (NET):	from 75 to 123 Kg. (@ size)
STANDARD NOISE LEVEL:	from 55 to 72 dB
NOISE PEAKS LEVEL: (every 5 minutes – 1 second duration)	from 79 to 81 dB

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RESIDUAL VALUES

STATEMENT OF CONFORMITY

We herewith declare that the quality titre of compressed air purified through the above mentioned drying unit **complies** with the minimum values foreseen by **European Pharmacopoeia**, which governs the recommendations of compressed air for medical use.

Residual values are as follows:

- **DEW POINT (@ at atmospheric pressure): - 46 °C**
- **DEW POINT (@ compressed air 9 bar(g): - 25 °C (*)**
- **RESIDUAL WATER VAPOUR: < 60 ppm_v**
- **RESIDUAL OIL AND V.O.S.: < 0,1 mg/m³, odour and taste free**
- **CARBON MONOXIDE (CO): < 5 ppm_v**
- **CARBON DIOXIDE (CO₂): < 500 ppm_v**
- **SULPHUR DIOXIDE (SO₂): < 1 ppm_v**
- **NITROGEN MONOXIDE NITROGEN DIOXIDE (NO₂): < 2 ppm_v**

(*) the Dew meter method on the ETHAFILTER units is by pressure at 9 bar(g)

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