

The manufacturer:

FATROMED S.r.l. - Via Case Rosse, 22 – 84131 Salerno – ITALIA – VAT IT 04173120652

Declares that the product identified as:

TRADE NAME: **ZEFIRO 300 - STERICLAIR**
 PRODUCT CODE: ZEFIRO 300 - STERICLAIR
 DESCRIPTION: Air recirculation unit with germicidal function based on UV-C, with UVGI principle (UltraViolet Germicidal Irradiation) for the reduction of bacterial and viral charge in the air.

IS COMPLIES with the provisions of the following EU directives:

- I. Direttiva 2014/30/EU: Electromagnetic Compatibility
- II. Direttiva 2014/35/EU: Low Voltage
- III. Direttiva 2006/42/CE: Machinery Directive

to which this declaration relates is in conformity with the relevant Union harmonisation legislation:

Referenece	Title and Description
CEI EN 60601-1	Medical electrical equipment - Part 1: General requirements
CEI EN 55014-1	Electromagnetic Compatibility - Requirements for household appliances - Part 1: Emission
CEI EN 55014-2	Electromagnetic Compatibility - Requirements for household appliances - Part 2: Immunity
CEI EN 62335-1	Safety of electrical appliances for domestic and similar use
CEI EN 62335-2-65	Household and similar electrical appliances - Safety - Part 2: Particular requirements for air-cleaning appliances
ISO 13485	Medical Devices Quality management systems, Requirements for regulatory purposes.
UNI EN ISO 9001	Quality management systems - Requirements
ISO 14971	Medical devices - Application of risk management to Medical Devices
IEC 82079-1	Preparation of instructions for use - Structuring, content and presentation - Part 1.
UNI 10653	Quality of product technical documentation
EN ISO 15223-1	Symbols to be used with medical device labels,
UNI EN 1041	Information supplied by the manufacturer of medical devices
CEI EN 17050-2	Supplier's declaration of conformity — Part 2: Supporting documentation
CEI EN 62023	Structuring of technical information and documentation
CEI EN 82045-1	Document management - Part 1: Principles and methods

Additional information EC declaration

1. The apparatus does not emit Ozone.
2. The trade name Nautilus, Zefiro 300, Stericclair, depending on the types of market.
3. The installation of the device must be carried out scrupulously respecting the technical parameters described in the use and maintenance manual (Security, Power supply, Wiring, Environment etc.).
4. The Conformity was declared on the basis of sample tests and with a set-up that reflects the functional configuration planned for its use.
5. The device is also conform at Directive 93/42 / EC.
6. The device: Nautilus - Zefiro 300 – Stericclair, **is property of ECS - Extra Corporeal Solutions s.r.l.** - Via Terre delle Risaie 20/A - 84131 Salerno – ITALY - VAT n° IT05161470652, that it's additionally responsible for the placing on the market.

Data di Emissione: 21.07.2020
 Data di Scadenza: 20.07.2025
 Numero Certificato: 03/20
 Revisione: Vers. 1.0
 Pagina: 1 di 1

General Manager
 Dr. Francesco Peluso
