

EU DECLARATION OF CONFORMITY

The manufacturer PEROXYMED SRL
REGISTERED OFFICE ADDRESS Via Brusuglio 52, 20161 Milan (MI)
SRN - UNIQUE REGISTRATION NUMBER IT-MF-000013643

DECLARES UNDER ITS SOLE RESPONSIBILITY THAT THE DEVICE:

Commercial name VIRO CLEAN EASY
CODE VR100-CL1
Basic UDI-DI 805750611MEDICALEQB – GS1 CODE 8057506110001
EMDN V07
BD/RDM recording 2159868

INTENDED USE The devices of the VIRO CLEAN SYSTEM series consist of atomizing machines for the diffusion of hydrogen peroxide-based disinfectant liquids which must be CE marked as medical devices.
We specifically recommend the use of the product “SUPRASPOR” (Class IIb medical device – RDM 2115296) tested, approved and distributed exclusively by PEROXYMED.
The devices are specifically intended to disinfect immovable medical devices located in hospital or healthcare environments.

DESCRIPTION The VIRO CLEAN SYSTEM device is an atomizer of medical device disinfectant products for the sanitization of immovable medical devices which is made up of:
• 1/2 bottles
• 1/2 very high-speed electric turbines
• 1/2 outlets / diffusers
depending on the model chosen:
1. VIRO CLEAN EASY
2. VIRO 2 CLEAN SYSTEM

The exit speed of the air from the nozzle which is produced by the electric turbine determines the production of a dry fog whose particles are smaller than 5 microns. The dry fog thus generated is distributed uniformly within the environment to be treated. This process saturates the atmosphere homogeneously with the chemical product used, guaranteeing optimal application on surfaces, without creating deposits and humidity. The VIRO CLEAN SYSTEM device was designed for the use, in the form of dry atomization, of CE marked hydrogen peroxide-based disinfectant liquids as medical devices for the disinfection of medical devices, in the absence of people (subject to verification of the technical data sheet and safety of the product used).

**IS ACCORDING TO:
TO REGULATION (EU) 2017/745**

CLASSIFICATION Class I (Annex VIII, Rule 13)
CONFORMITY ASSESSMENT PROCEDURE Attachments II and III

**AND THE FOLLOWING LEGISLATIVE ACTS THAT PROVIDE FOR THE RELEASE
OF AN EU DECLARATION OF CONFORMITY:**

Directive 2012/19 / EU on waste electrical and electronic equipment (WEEE / RAEE)

RoHS Directive 2011/65 / EU (See Annex I)

Date and place of issue of the
declaration of conformity.

Milan, January 10, 2024

Legal Representatives

Angelo Ernesto Rinaldi



Annex I

Declaration of Conformity to EU RoHS

Products are in compliance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (also known as "RoHS Recast"). In addition, this declaration of conformity is issued under the sole responsibility of the manufacturer, specifically, products manufactured do not contain the substances listed in the table below in concentrations greater than the listed maximum value.

This declaration also implements the COMMISSION DELEGATED DIRECTIVE (EU) 2021/1980 of 11 August 2021.

Substance	Maximum Limit %
Leads	0.1
Mercury	0.1
Cadmium	0.01
Hexavalent chromium	0.1
Polybrominated biphenyls (PBB)	0.1
Polybrominated diphenyl ethers (PBDEs)	0.1
Bis(2-ethylhexyl) phthalate (DEHP)	0.1
Butyl benzyl phthalate (BBP)	0.1
Dibutyl phthalate (DBP)	0.1
Diisobutyl phthalate (DIBP)	0.1

Milan, January 10, 2024

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