

## **EU DECLARATION OF CONFORMITY**

MANUFACTURER PEROXYMED s.r.l.

REGISTERED OFFICE ADDRESS Via Brusuglio 52, 20161, Milano (MI) - Italy

DECLARES UNDER ITS SOLE LIABILITY THAT THE DEVICE:

2159868 **BD/RDM REGISTRATION** 

VIRO2 CLEAN EASY - VERS. K1 COMMERCIAL NAME **UDI-DI** Base 805750611MEDICALEQB

V07 - PRODUCTS FOR CLEANING MEDICAL DEVICES NOT INCLUDED IN OTHER

**CND CLASSES** 

INTENDED USE

DESCRIPTION

The devices of the VIRO CLEAN SYSTEM series consist of atomising machines for the

diffusion of disinfectant liquids based on hydrogen peroxide of the NTOXY line developed by PEROXYMED s.r.l. These are devices for the atomized sanitization of

surfaces and devices in hospitals using "dry fog" technology.

The VIRO CLEAN EASY device is an atomizer for chemical products which consists

of:

• 1 bottle

• 1 very high speed electric turbine

• 1 union / diffuser

The exit speed of the air from the nozzle that is produced by the electric turbine causes the production of a dry fog whose particles are less than 5 microns.

The dry fog generated in this way is uniformly distributed within the environment

to be treated. This process saturates the atmosphere homogeneously with the chemical product used, ensuring optimal application on surfaces, without creating

deposits and humidity.

The VIRO CLEAN EASY device has been designed for the use, in the form of dry atomization, of disinfectant chemical products (such as hydrogen peroxide) for the treatment of confined spaces, in the absence of people (after checking the technical

data sheet and safety of the product used).

## **IS ACCORDING TO:**

**REGULATION (EU) 2017/745** 

CLASSIFICATION Class I MEDICAL DEVICE (Ann. VIII regola 13)

**CONFORMITY ASSESSMENT** 

Ann. II e III **PROCEDURE** 

> AND TO THE FOLLOWING LEGISLATIVE ACTS WHICH PROVIDE FOR THE RELEASE OF AN EU DECLARATION OF CONFORMITY:

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

PEROXYMED s.r.l. - **P.I.** IT11312350967 Via Brusuglio 52 - 20161 MILANO (MI) Italia - Web: www.peroxymed.it Tel: +39.039.6777556 - +39.324.7404765 - Codice univoco SDI: M5UXCR1

- Mail: info@peroxymed.it

ORGANIZATION WITH QUALITY MANAGEMENT SYSTEM ISO 13485:2016 CERTIFIED by EuCI European Certification Institute LTD

Certificate N.:BDBR326202102 ORGANIZATION WITH QUALITY MANAGEMENT SYSTEM
ISO 9001:2015 CERTIFIED by
EUCI European Certification Institute LTD

## Peroxymed s.r.l.



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

Date and place of issue of the declaration of conformity

Milan, July 19th 2021

Legal Representative 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 issued under the sole responsibility of the manufacturer, specifically, products manufactured do not contain the substance is listed in the table below in concentrations greater than the listed maximum value.

This declaration also implements the COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU.

| Substance                           | Maximum Limit % |
|-------------------------------------|-----------------|
| Lead                                | 0,1             |
| Mercury                             | 0,1             |
| Cadmium                             | 0,1             |
| Hexavalentchromium                  | 0,1             |
| Polybrominatedbiphenyls (PBB)       | 0,1             |
| Polybrominateddiphenylethers (PBDE) | 0,1             |
| Bis(2-ethylhexyl) phthalate (DEHP)  | 0,1             |
| Butylbenzylphthalate (BBP)          | 0,1             |
| Dibutylphthalate (DBP)              | 0,1             |
| Diisobutylphthalate (DIBP)          | 0,1             |