ULTRAVIOL
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Date: 27.06.2023

For:
"Pharmony" S.R.L.
4, Durlesti Str., Durlesti town,
Chisinau, MD2071, Republic of Moldova

To whom it may concern

Declaration of classification

We:
ULTRA-VIOL Sp.j. Pietras, Purgał, Wójcik
Stępowizna 34 Str.
95-100, Zgierz, Poland

Digitally signed by Şarco Alexandru
Date: 2023.07.20 15:41:33 EEST
Reason: MoldSign Signature
Location: Moldova

Declares that:

The current European guidelines do not recognize bactericidal lamps as medical devices – please see attachment no 1: the MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.19 (04-2018) - 1.13. Air purifiers / Air decontamination units / Mobile air decontamination units on pages 17-18 and 1.23 UV flow germicidal lamp on page 23.

Following the above-mentioned guidelines, the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products in Poland (Polish competent authority) has changed its previous interpretation of the statutory definition of medical devices and as a result of this change, an administrative decision has been issued that recognizes bactericidal lamps as non-medical devices. This decision does not undermine the effectiveness and need of using germicidal lamps in the health sector but changes the formal approach of the Office to these products and their manufacturers.

Please note that although we cannot declare compliance with the Medical Directive, we still comply with its all procedures and can confirm compliance with the medical safety standard EN 60601-1 in the EC Declaration of Conformity.

The germicidal lamps are electrical devices that conform to the essential requirements stated in the following EC – Directives:

- **2014/35/EC (LVD),**
- **2014/30/EC (EMC),**
- **93/42/EEC and 2007/47/EC (some requirements).**

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The devices conform to the harmonized European standards:

• **EN 60601-1**	**Medical electrical equipment** -- Part 1: General requirements for basic safety and essential performance
• **EN 60601-1-2**	**Medical electrical equipment** – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
• **EN 60335-2-65**	Household and similar electrical appliances - Safety - Part 2-65: Particular requirements for air-cleaning appliances
• **EN 60335-1**	Household and similar electrical appliances – Safety – Part 1: General requirements
• **EN 61547**	Equipment for general lighting purposes - EMC immunity requirements
• **EN 60529**	Degrees of protection provided by enclosures (IP code)

We declare with full responsibility that the products meet the requirements of the **RoHS directive 2011/65/EU** (including all its changes and amendments). Conformity assessment was carried out according to standard **EN 50581**.

Quality Management System of ULTRA-VIOL certified by TUV Nord meets the requirements of:

- **EN ISO 13485:2016 - Medical devices** – Quality management systems – Requirements for regulatory purposes

In the context of INTEGRATED TARIFF INFORMATION SYSTEM classification
the germicidal lamps have the following HS/CN code:

90182000 - Ultraviolet or infra-red ray apparatus

We would like to emphasize that according to the above-mentioned regulations, none of the UV-C lamps and sterilizers produced within the territory of the EU can be classified as medical devices.

List of attachments:

1. Manual on borderline and classification in the community regulatory framework for medical devices Version 1.19 (04-2018)
2. Declaration of conformity for GERMIPROTECT series

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Yours Sincerely,

Wiesław Pietras
General Manager