Recopilación de certificaciones de los dispositivos de emisión de UVC lejana

1. Certificado de cumplimiento de la normativa ISO15858:2016 referido a los dispositivos UV-C, información de seguridad y límites de exposición humana.

Estos dispositivos están diseñados para ser utilizados en presencia de personas

- 2. Declaración de conformidad europea (marcado CE) necesaria para la comercialización de dispositivos referida a la compatibilidad electromagnética (Directiva 2014/30/EU), a la puesta a disposición de equipos eléctricos diseñados para el uso con ciertos límites de voltaje (Directiva 2014/35/EU) y la Directiva RoHS (2011/65/EU) referida a la restricción de uso de ciertas sustancias peligrosas en equipos eléctricos y electrónicos.
- 3. Documento emitido por la Universidad danesa de Aarhus donde se establecen los criterios para el uso seguro en espacios ocupados de las lámparas que emiten UVC lejana.
- 4. No son dispositivos médicos sino creados con la finalidad de desinfectar aire y superficies.

La Agencia Médica de Dinamarca, de acuerdo con su regulación de dispositivos médicos, asegura que no se pueden clasificar como tal.

Del mismo modo, el fabricante, con sede en Dinamarca, solicitó este reconocimiento a la Confederación de Industria de su país, que le emitió el certificado adjunto asegurando dicha finalidad y que no se trata de este tipo de dispositivos.

5. Certificado ISO9001:2015 como diseñadores y fabricantes de soluciones de UVC lejana.



To whom this may concern

December 17, 2021

UV222[™] lamps in compliance with ISO 15858

This letter confirms that the lamps **UV222[™]** from the Danish company **UV Medico A/S** are in compliance with the **ISO 15858**. The UV222[™] are **filtered KrCl excimer lamps** with a central emission at a wavelength of **222 nm**.

The ISO 15858 is an international regulation for "UVC devices, safety information, and permissible human exposure". UVC is defined as part of the electromagnetic spectrum with wavelengths in the range 200–280 nm. This ISO standard is applicable to any UVC devices which may cause UVC exposure to humans. In particular, it describes the **threshold limit values (TLVs)**, which are guidelines on UVC exposure level under which most people can work consistently for **8 hours a day**, day after day, without adverse effects. Specifically, **Article 5.2** of the ISO 15858 indicates that the maximum permissible UVC exposure shall not exceed the TLVs prescribed by the American Conference of Governmental Industrial Hygienists (**ACGIH**).

The relevant publication from the ACGIH is the **2021 edition** of the "Threshold Limit Values (TLVs[®]) and Biological Exposure Indices (BEIs[®])". Specifically, the section "Threshold Limit Values -> Optical Radiation -> Ultraviolet Radiation" on **pages 152–157** defines a **spectral weighting function** *S* which considers the wavelength dependence of the health effects of UV radiation on eye and skin. Its values are listed in Table 1 on page 154. For a wavelength of 222 nm: *S* = **0.1316**.



Aarhus University Finlandsgade 22 8200 Aarhus N Denmark

Phone: +45-9352-2084 Email: volet@ece.au.dk Web: ece.au.dk/integrated-photonics For what follows three physical quantities are defined:

- the irradiance is the radiant power incident per unit area upon a surface, expressed in watts per square meter [μW / cm²];
- the radiant exposure H is the time integral of the irradiance, expressed in joules per square meter [mJ / cm²];
- the **effective radiant exposure** H_{eff} is the radiant exposure spectrally weighted by $S(\lambda)$, expressed in joules per square meter [mJ / cm²].

According to the ACGIH, for a daily exposure of **8 hours**, the **effective radiant exposure should be smaller than:**

$$H_{\rm eff}$$
 = 3 mJ/cm².

This means that the **radiant exposure** for the UV222[™] lamps should be smaller than:

$$H = 3 \text{ mJ/cm}^2 / 0.1316 \approx 23 \text{ mJ/cm}^2$$
.

If the UV222[™] is **turned on continuously for 8 hours**, its **irradiance** *I* (optical power per unit area) should then be smaller than:

$$I = 23 \text{ mJ/cm}^2 / (8*60*60 \text{ s}) \approx 0.80 \,\mu\text{W/cm}^2$$
.

Every UV222[™] lamp from UV Medico is characterized by a UV-calibrated goniometer which measures the spatial and the spectral irradiance distribution. For a given distance from the lamp, the light irradiance is maximal at the center position normal to the front glass. In addition, as the distance from the lamp increases, the irradiance decreases. At one meter from the lamp, the maximum irradiance is:

$/ \approx 13 \ \mu W/cm^2$.

This value is larger than the irradiance (of 0.80 µW/cm²) corresponding to the TLV. This is in fact the case for distances up to about 4 meters. Therefore, the UV222[™] lamps would exceed the TLV if they are turned on continuously. For this reason, every UV222[™] lamp is configured with a software to run in **duty cycles** with a specific on/off ratio. This ratio considers the lamp placement in the specific room along with the occupant time of the room. From these parameters the on/off ratio required to conform with the ISO 15858 is computed and the UV222[™] lamps are turned on and off in an alternate way and automatically, to **ensure the accumulated dose never exceeds the TLV** at any height between the room floor and 180 cm (standard eye height).



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Phone: +45-9352-2084 Email: volet@ece.au.dk Web: ece.au.dk/integrated-photonics As supplementary safety precautions, each lamp is equipped with a LIDAR (providing 16-point distance measurements) along with a PIR movement sensor. The lamp is configured to shut off should anything come within a pre-defined safety distance. The movement sensor is used in situations where the lamp is configured to be turned on outside of occupant hours, the sensor here assuring that the room is indeed empty.

Should you require any additional information, please use my contact information provided at the bottom of the letter.

Sincerely,

N. Vola

Nicolas Volet Assistant Professor



Aarhus University Finlandsgade 22 8200 Aarhus N Denmark

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EU Declaration of Conformity

Manufacturer	UV Medico A/S Søren Frichs Vej 40E, st 8230 Åbyhøj Denmark CVR: 41273135
Object of the declaration	Germicidal Compact Far UV light Type: UV222 FAR UVC light and surface purifier
The described product is in conform	nity with the relevant Union harmonisation legislations
ROHS Directive 2011/65/EU and amendments	Directive 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.
LVD 2014/35/EU	Directive of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.
EMC Directive 2014/30/EU	Directive of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility.
The conformity of the designated p the compliance with the following It not elsewhere/otherwise indicat	product with the provisions of European Directives is given by European Standards or other specifications. ed the edition/amendment as referenced below applies.
RoHS	EN 50581 :2012 Technical documentation for the assessment of electrical and electronic product with respect to the restriction of hazardous substances
LVD	EN 60335-2-65:2003 + A1 :2008 + A 11 :2012 Household and similar electrical appliances - Safety- Part 2-65: Particular requirements for air-cleaning appliances
	EN 60335-1 :2012 + A11 :2014 + A13:2017 Household and similar electrical appliances - Safety - Part 1: General requirements
EMC	EN 62233:2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus about human exposure.



EN 61000-3-2: 2014

Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current: 16 A per phase).

EN 61000-3-3: 2013

Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current: 16 A per phase and not subjected to conditional connection.

EN 55014-1 :2017

Electromagnetic compatibility - Requirements for household appliances, electric tools, and similar apparatus - Part 1: Emission. EN 55014-2:2015

Electromagnetic compatibility - Requirements for household. appliances, electric tools, and similar apparatus - Part 2: Immunity - Product family standard.

List of additional Standards the product is compliant to:

ISO 15858	UV-C Devices – Safety information – Permissible human exposure.
IEC 62471	Photobiological safety of lamps and lamp systems.
EC PAS 63313 ED1	Position statement on germicidal UV-C irradiation - UV-C safety guidelines.
ACGIH [®] (American Conference of Governmental Industrial Hygienists)	2021 TVL (Threshold Limit Values) & BEI (Biological Exposure Indices) for chemical substances and physical agents.

This declaration conformity is used under the sole responsibility of the manufacturer UV Medico A/S.

Signature on behalf of UV Medico A/S, 28/04/2021, Aarhus, Denmark.

Anders Samuelsen CEO

Peter Johansen Chairman



To whom this may concern

February 4, 2022

Criteria for far-UVC lamps to be used safely in occupied spaces

Under specific conditions described in this document, krypton-chloride (KrCl) excimer lamps can be used safely in the presence of people. If these conditions are not met, these lamps can be harmful. It is therefore important that all the following criteria are rigorously verified.

- 1) The fraction of the total UV emission that is within the wavelength range 200–230 nm is larger than 95 %.
- 2) For operation times shorter than one hour, the fluctuation of irradiance is smaller than 5 % of the stable initial value.
- 3) The lifetime is at least 10'000 hours.
- 4) The accumulated dose delivered by the lamp does not exceed the threshold limit value in any area of the room where people could potentially be present and for any height between the room floor and 180 cm (standard eye height).

These criteria are explained in the rest of this document. The relevant International Standard is the **ISO 15858:2016**, entitled: "UV-C Devices — Safety information — Permissible human exposure". It is applicable to any devices which may cause UVC exposure to humans. Article 4.3 of the ISO 15858:2016 states that UVC radiation measurement shall comply with the measuring method described in the European Standard **EN 14255-1:2005**, entitled "Measurement and assessment of personal exposures to incoherent optical radiation". The optical spectra of the UV222[™] lamps from UV Medico are measured with a spectrometer from the company Ibsen, model "HR-UV / C-UV". Measurements of irradiance and spatial distributions are obtained with



a goniometer from the company Viso Systems, model "LabSpion UV-VIS". Both instruments are traceable to NIST calibration light sources.

— Emission spectrum

Far UVC is defined as the wavelength range between 200 nm and 230 nm. KrCl excimer lamps have a main emission centered near 222 nm. However, they also emit secondary emissions near 235 nm and near 255 nm. Light at wavelengths longer than 230 nm can efficiently penetrate the top layer of the skin (*stratum corneum*) and the top layer of the eye (cornea), causing damages in the underneath living cells. These longer wavelengths are harmful and must be suppressed if the lamps are to be used in occupied spaces. This can be achieved by using an optical band-pass filter which transmits 222 nm and blocks wavelengths longer than 230 nm. This idea is protected by a patent filed by Columbia University (USA), for which the company Ushio has a worldwide exclusive license. KrCl excimer lamps also emit wavelengths below 200 nm. Interaction of ambient oxygen with light at these wavelengths may produce ozone. In humans, ozone can irritate nasal passages, cause nausea and extended exposure can lead to lung inflammation. These shorter wavelengths must therefore also be suppressed. One needs to measure the fraction of the total UV emission that is within the safe wavelength range of 200–230 nm. **One requires this fraction to be larger than 95 %**.



Figure 1: (a) Emission spectrum of a UV222[™] lamp from UV Medico. (b) Spectrum plotted in logarithmic scale. Most of the emission is in the safe far-UVC (200–230 nm, in green).
 Wavelengths that are potentially harmful are suppressed (<200 nm and >230 nm, in red).



Figure 1(a) shows the spectrum of a UV222[™] lamp from UV Medico. The main emission is centered at 221.9 nm, with a full width at half maximum (FWHM) of 1.9 nm. Figure 1(b) shows the same spectrum plotted in logarithmic scale. The part in green is in the far UVC and corresponds to **96.2** % of the total UV emission. Parts shown in red are much weaker and correspond to shorter wavelengths (<200 nm) and longer wavelengths (>230 nm).

--- Stability in output power and lifetime

Right after switching on the lamp, the output power may fluctuate as it needs some time to stabilize. Stable operation is reached after about 12 seconds. After this initial period, the output power still varies over time. It is important to fix criteria on the acceptable fluctuation of power. For operation times shorter than one hour, one requires this change to be smaller than 5 % from the stable initial value.

In addition, after a certain amount of time, called the lifetime, lamps must be replaced. The lifetime is defined at the time it takes for the output power to reach 50 % of the stable initial value. **One requires the lifetime to be at least 10'000 hours.**

— Maximum permissible dose

Article 5.2 of the ISO 15858:2016 indicates that the maximum permissible UVC exposure shall not exceed the threshold limit values (TLVs) prescribed by the American Conference of Governmental Industrial Hygienists (ACGIH). TLVs consider the wavelength dependence of the health effects of UV. They apply to exposure of the cornea and provide conservative guidelines for skin exposures. They are guidelines on UVC exposure level under which most people can work consistently for eight hours a day, day after day, without adverse effects. The relevant publication from the ACGIH is the 2021 edition of the "Threshold Limit Values (TLVs[®]) and Biological Exposure Indices (BEIs[®])". Specifically, in the section "Threshold Limit Values –> Optical Radiation –> Ultraviolet Radiation" on pages 154–155 are listed the TLVs for ultraviolet radiation. For convenience, these values are plotted in Figure 2(a). For a wavelength of 222 nm, the TLV is **23 mJ/cm²**.





Figure 2: (a) Threshold limit values (TLVs) as listed in the 2021 edition of the ACGIH. (b) Far-UVC irradiance at the center of the emission beam plotted as a function of the distance from the UV222[™] lamp. The solid line is a fit for an inverse squared law.

Several safety measures are needed for the lamp not to exceed the TLV. In addition to the spectral composition described in Figure 1, the irradiance needs to be measured for all angles and distances. Every UV222[™] lamp from UV Medico is characterized by a UV-calibrated goniometer which measures the spatial and the spectral irradiance distribution. For a given distance from the lamp, the irradiance is maximal at the center position normal to the front glass. In addition, as the distance from the lamp increases, the irradiance decreases, as seen in Figure 2(b). For most rooms, the UV222[™] lamps would exceed the TLV if they are turned on continuously. For this reason, every UV222[™] lamp is configured with a software to run in duty cycles with a specific on/off ratio. This ratio considers the lamp placement in the specific room along with the occupant time of the room. From these parameters the on/off ratio required to conform with the ISO 15858:2016 is computed and the UV222[™] lamps are turned on and off in an alternate way and automatically, to **ensure the accumulated dose never exceeds the TLV** in any area of the room where people could potentially be present and for any height between the room floor and 180 cm (standard eye height).

As supplementary safety precautions, each lamp is equipped with a motion detector and a distance sensor. In situations where the lamp is configured to be turned on outside of occupant hours, the motion sensor assures that the room is indeed empty. Finally, the lamp is configured to shut off should anything come within a pre-defined safety distance.



The task of ensuring safe operation requires expert knowledge of the lamp emission, its placement in the room and the behavioral pattern of the people in the room. Therefore, the UV222TM should be installed by qualified professionals with little to no options for the end-user to alter lamp settings.

Should you require any additional information, please use my contact information provided at the bottom of the letter.

Sincerely,

N. Va

Nicolas Volet Assistant Professor





23 May 2022 Case no. 2022053597

Anders Samuelsen CEO UV Medico A/S Søren Frichs Vej 40E, st 8230 Åbyhøj - Denmark

Regarding UV222 lamps for disinfection of air and surfaces.

In the Danish Medicines Agency's opinion, UV222 lamps <u>should not be considered</u> <u>as a medical device</u> as the purpose of the product is disinfection of air and surfaces.

According to article 2 in the Medical Devise Regulation (2017/745) only products specifically intended for cleaning, disinfection or sterilization of other medical devices, should be considered as medical devices – and this is not relevant in this particular case.

Best regards

Jamie Saul

Jannie Wiegand Storgaard

Danish Medicines Agency Axel Heides Gade 1 2300 Copenhagen S Denmark T +45 44 88 95 95 E dkma@dkma.dk LMST.DK



-/mema

Dansk Industri Confederation of Danish Industry

TO WHOM IT MAY CONCERN

We, Confederation of Danish Industry, do hereby certify, on the basis of documentary evidence produced before us, that the company

> UV Medico A/S Søren Frichs Vej 40E, st. DK- 8230 Åbyhøj, Denmark

is a company duly existing under the laws of the Kingdom of Denmark. We also certify that the above company is known to us as worthy of confidence.

The aforesaid company is entitled to engage in the business of manufacturing and exporting ultraviolet light fixtures for germicidal purposes. These devices are not classified as medical devices.

The company is registered under CVR No. 42602582 in the Central Business Register (CVR) of Denmark*

In evidence hereof Confederation of Danish Industry affixes its signature and stamp on this document this 18th day of May, 2022.



* The Central Business Register (CVR) is the central register containing primary data on all businesses in Denmark, regardless of economic and organizational structure. CVR also covers both public and private businesses. In addition, CVR contains detailed information on all limited companies, including fiscal reports, management and financial information and status, etc.

H. C. Andersens Boulevard 18 1787 København V Danmark (+45) 3377 3377 di@di.dk di.dk

IS@accelerator

Certificate of Registration

This is to certify that the Quality Management System of:

UV Medico A/S Søren Frichs Vej 40E, st 8230 Åbyhøj Denmark



Authorised By:

Elisabeth Inns

Elisabeth Inns, Global Assurance Director







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