Risk assessment

UV Recycling bin for used face masks

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Manufacturer:	GMAF Circular Medico ApS	Review:	2
Description:	UV Recycling bin for used face masks	Review date:	June 16th 2021
Reference:	05583	Initials:	MVL

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Introduction

The purpose of this risk assessment is to verify the safe construction of the equipment and study the compliance of the equipment including the power supply with the Low Voltage Directive 2014/35/EU.

The content of the risk assessment is provided in accordance with EN ISO 12100 and performed with guidance from CENELEC guide 32 - Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment.

The Low Voltage Directive 2014/35/EU article 3, states that:

"*Electrical equipment may be made available on the Union market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Union, it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made.*"

The principal elements of the safety objectives are listed in Annex I.

"*Before placing equipment on the market and/or putting it into service, the manufacturer or his authorised representative shall:*

(a) *ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;"*

To determine compliance between the equipment and the Low Voltage Directive, the design of the equipment will be assessed regarding the essential health and safety requirements set out in Annex I. The risk assessment will contain documentation regarding all the relevant essential health and safety requirements. Where the equipment is lacking regarding health and safety, a suitable solution is provided to bring the equipment into conformity.

Annex A (3) of the CENELEC guide 32 states that all hazards present on the equipment shall be mitigated in accordance with the safety principles described below:

> "*In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:*
>
> *— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),*
>
> *— take the necessary protective measures in relation to risks that cannot be eliminated,*
>
> *— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment."*

Furthermore, the reader is presumed to have a basic understanding of the equipment in case. If this is not the case, a description of the equipment can be found in Appendix B - Information for risk assessment.

Finally, to ease the workload of the designers – a conclusion has been included and can be found in Appendix A – Conclusion. The conclusion contains necessary control measures, if any, that needs to be carried out for the equipment to achieve conformity.

Determination of limits of equipment

The following information has been included in accordance with EN ISO 12100 section 5.3. This clause will determine the limits of the equipment in all the applicable phases. All content of this clause is a prerequisite for the validity of the risk assessment.

Use limits

The equipment is intended for disinfecting used face masks. The functionality of the equipment is limited to the intended use.

Operating modes and intervention procedures

The following operating modes and intervention procedures have been identified on the equipment:

Normal mode:
The equipment is used for disinfecting used face masks by using UV illumination.

When bacteria or another type of microbe is exposed to certain types of UV light, these bacteria and virus are killed. When the face masks have been disinfected with UV light, they are no longer categorized as hazardous waste and can be recycled.

Intervention procedure for maintenance or repair:
When service is required – the technician shall ensure, that the electrical supply is disconnected.

User area and personnel

The equipment will operate in public institutions, e.g., at hospitals, clinics, and medical practices. It can be nondomestic area.

The equipment is used by all persons with the knowledge of the functionality of the equipment. Any disabilities and handicaps do not necessarily exclude any users.

Level of training, experience, or ability

The following personnel and required training/experience levels have been identified for the equipment:

Operator/maintenance personnel
Operators are expected to have read and understood the user manual.

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Space limits

The following space limits are mentioned for the purpose of general safety for all personnel. Space limits are intended for improving emergency egress and ergonomics.

Space requirements for persons interacting during operation or maintenance
Personnel interacting with the equipment on a daily basis shall be provided with enough space to stand upright with a minimum head-height of 2100 mm in accordance with EN ISO 14122-2 section 4.2.2.

Human interaction
The user shall provide enough space around the equipment for an operator to use the equipment in an ergonomic position between 500 mm and 1700 mm above the working surface in accordance with EN ISO 14122-2 section 4.2.1.

Equipment power-supply interface
The user shall provide enough space around the equipment for the power supplies to be installed in close proximity to the equipment, without breaking any of the abovementioned space requirements.

Time limits

The users of the equipment shall comply with the following time limits and service intervals to maintain the validity of the risk assessment.

Lifetime of equipment and/or components taking intended and unintended use into account
The equipment is expected to run indefinitely but this risk assessment is based on a 20-year lifetime. That means that the equipment shall be subject to a new risk assessment after 20 years to determine whether components shall be changed or not.

Recommended service interval
Key service intervals shall be included in the user manual. It is a prerequisite for this risk assessment that the service intervals for all components are maintained in accordance with the supplier's datasheets, user manuals etc.

Other limits

The following properties, limits and demands are prerequisites for the validity of the risk assessment.

Environmental

The prerequisites for the environmental values are found in the below table:

Property	Value and unit if applicable
Area	Indoor
Temperature range	5°C - 40°C
Allowable relative humidity	min. 20 % - max. 80 %

Housekeeping

A regular level of cleanliness is required. The equipment is not prone to malfunctioning due to minor dust accumulation. Spillage of product etc. shall be cleaned immediately. If required, the equipment shall be installed in a hygienic environment to ensure sterile production.

Properties of materials to be processed

The equipment will handle used face masks for recycling.

Hazard identification

To evaluate the design of the equipment, all hazards shall be identified in accordance with EN ISO 12100. To identify all the hazards on the equipment, all phases of the equipment are to be revised. Hazards that arise during rare scenarios or certain phases, tasks or malfunctions are all to be included.

Primarily, alongside Annex B of EN ISO 12100, the following is taken into account when determining hazards present:

a) Human interaction during the whole life cycle of the equipment
   a. Setting
   b. Testing
   c. Teaching/programming
   d. Process/tool changeover
   e. Start-up
   f. All modes of operation
   g. Feeding the equipment
   h. Removal of product form the equipment
   i. stopping the equipment
   j. stopping the equipment in case of emergency
   k. recovery of operation from jam or blockage
   l. restart after unscheduled stop
   m. fault-finding/troubleshooting (operator intervention)
   n. cleaning and housekeeping
   o. preventive maintenance
   p. corrective maintenance

b) Possible states of the equipment
   a. the equipment performs the intended function (the equipment operates normally)
   b. the equipment does not perform the intended function (i.e., it malfunctions) due to a variety of reasons

c) Unintended behaviour of the operator or reasonably foreseeable misuse of the equipment
   a. loss of control of the equipment by the operator (especially for hand-held or mobile equipment),
   b. reflex behaviour of a person in case of malfunction, incident, or failure during the use of the equipment,
   c. behaviour resulting from lack of concentration or carelessness,
   d. behaviour resulting from taking the “line of least resistance” in carrying out a task,
   e. behaviour resulting from pressures to keep the equipment running in all circumstances, and
   f. behaviour of certain persons (for example, children, disabled persons).

To decrease repetitiveness, the explanations of the specific hazard scenarios are included in the clause “Risk estimation, evaluation and reduction”.

Risk estimation, evaluation, and reduction

This clause includes a complete hazard identification. Every hazard identified will contain:

1. **Risk estimation**
   This part analyses the extent of the possible accident. Thus, evaluating the severity of the potential harm and the probability of occurrence. The probability of occurrence is a function of
   a. The exposure of person(s) to the hazard
   b. The occurrence of a hazardous event, and
   c. The technical and human possibilities to avoid or limit the harm
2. **Risk evaluation**
   After estimating the risks, an evaluation is to be carried out to determine whether a risk reduction is necessary or not. The evaluation is based on:
   a. Comparable equipment
   b. Harmonized C-standards
3. **Risk reduction**
   If the equipment is lacking in regard to the directive – a risk reduction / design change has to be implemented. The risk reduction will, as described in Introduction, be based on the principles of Annex A (3) of the CENELEC guide 32.

All the hazards are presented with a reference number (starting from 1) and the respective section of the CENELEC guide 32 Annex A, which applies.

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1. Risks associated with against electrical hazards – A.4

Hazard and risk estimation

Use of incorrect connection of supply voltage, current or frequency. Using an incorrect voltage, current or frequency, the components may malfunction and possibly catch fire.

In case of contact with conductive parts, people may suffer from electrical shock, which may cause internal burns, heart failure and death.

In particular, the equipment shall provide adequate protection against electrical hazards, arising from:

a) leakage current;
b) energy supply;
c) stored charges;
d) arcs;
e) electric shock;
f) burns.

Risk evaluation and reduction

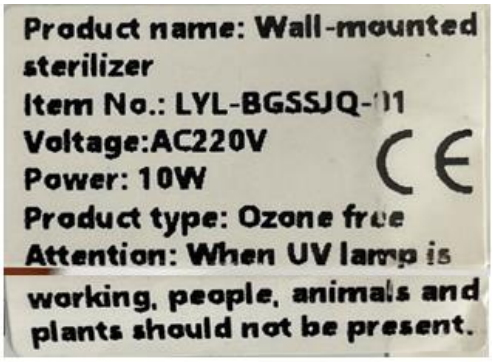
The electrical design has been carried out according to EN 60598-1:2015 - Luminaires - Part 1: General requirements and tests. The design has been verified by the notified body UDEM and signed in the certificate M.2020.206.C5150.

The equipment is designed within electrically insulating material and are to be opened with a tool before accessing live parts.

Cable terminals and cable are fitted with strain relief clamp and mounted with good engineering practice.

The manufacturer informs the user of the voltage, current, frequency and IP-class that the equipment is connected to. This information must be provided at the nameplate, the technical documentation, and the instruction manual.

The luminaires are marked according to EN 60598-1 section 3.2:



Action required: No

2. Risks associated with instability – A.5.a

Hazard and risk estimation
The equipment tips and overturns. Persons may be hit by falling equipment.

Risk evaluation and reduction
The equipment is sufficiently stable to prevent it from tipping over, disassembling, or causing uncontrolled movements during any action to which the equipment is subjected.

The weight of the container is approximately 12-13 Kg.

The instructions state that:

The equipment shall be placed stably on a flat surface.

Action required: No

3. Risks associated with break-down during operation – A.5.b

Hazard and risk estimation
The equipment cannot withstand the mechanical impacts that it is exposed to during normal use. Live parts can be available for direct or indirect contact, which can lead to electric shock with additional injuries.

Risk evaluation and reduction
The equipment is estimated to withstand the expected mechanical impacts during operation.

Action required: No

4. Risks associated with inadequate surfaces, edges, or corners – A.5.d

Hazard and risk estimation
Rough surfaces, sharp edges, and corners throughout the equipment extent. Contact with rough surfaces, sharp edges and corners can cause injuries to operators.

Risk evaluation and reduction
All surfaces are smooth, and edges are rounded, i.e. There are no rough surfaces or sharp corners accessible.

Action required: No

5. Risks associated with vibration – A.5.f

Hazard and risk estimation
Loose wires or electrical components due to the vibrations that the socket outlets and junction boxes are exposed fore. Exposed parts, interfaces and metallic parts may be energized, which can lead individuals who touches those parts, electric shock.

Risk evaluation and reduction
The equipment and its connections are suitable to withstand the vibrations to which it may be exposed during normal use. All components in junction box are, securely and firmly fitted.

Action required: No

6. Risks associated with improper fitting of parts – A.5.g

Hazard and risk estimation
Danger of incorrect assembly of cables. Connecting incorrect voltage to components can result in mechanical or electrical injuries.

Risk evaluation and reduction
The instructions give information on replacement of fluorescent tubes.

Action required: No

7. Hazards arising from electric, magnetic, and electromagnetic fields, other ionizing and non – ionizing radiation / Electric, magnetic, or electromagnetic disturbances – A.6.3 / A6.4

Hazard and risk estimation
Electromagnetic radiation from or to external sources may affect the operation of the equipment and ultimately affect the health and safety of persons. Electromagnetic noise may cause malfunction of the equipment other equipment nearby.

Risk evaluation and reduction
The electrical equipment requires immunity and emission test unless the following conditions are fulfilled:

- The incorporated devices and components comply with the EMC requirements for the intended EMC environment specified in the relevant product standard.
- The electrical installation and wiring are consistent with the instructions provided by the supplier of the devices and components with the regard to the mutual influences.

Solution example:
By solely using CE-marked products and installing them in accordance with the supplier's instructions the equipment will be in accordance with the abovementioned requirements.

Action required: No

8. Optical radiation – A.6.5

Hazard and risk estimation
Exposure to UV light can over time cause photochemical damage and thermal damage to the eyes and erythema to the skin.

Risk evaluation and reduction
The variation of ultraviolet used in this equipment is the type UVC (100-280 nm).

The equipment is designed and constructed so that exposure to hazardous optical radiation does not occur.

The light source is placed within the container and the lid is locked with a padlock to restrict access.

Therefore, personnel are during normal operation not exposed to optical radiation exceeding the limits in accordance with Directive 2006/25/EC - minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).

On the equipment a warning sign against optical radiation shall be fitted.

Risk of optical radiation

Inside the container, there is a risk of optical radiation.

Be sure to disconnect the equipment before opening the container.

Action required: No

9. Temperature – A.6.6

Hazard and risk estimation

Components that becomes hot during operation. Contact to the hot surfaces can cause, burn, discomfort and result in sudden movements to avoid burns.

Risk evaluation and reduction

All components that might get hot are guarded within the light fixture and they cannot be reached.

The light source itself does not get hot during normal operation. A temperature at 40 ^{o}C was measured over a period of one hour.

Action required: No

10. Biological and chemical effects – A.6.8

Hazard and risk estimation

Hazards can arise from:

a) Microbiological causes such as pathogens, spoilage, micro-organisms, or toxins; for example, ingress or retention of bacteria, spores, viruses, yeasts, and moulds.
b) Chemical causes including those from cleaning and disinfecting substances; for example, cleaning fluids.
c) Foreign materials arising from raw materials, equipment, or other causes; for example, allergens, pests, metals, and materials used in the construction of the equipment.

Risk evaluation and reduction

The RoHS Directive requires heavy metals such as lead, mercury, cadmium or hexavalent chromium and flame retardants such as polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) to be replaced by safer alternatives. As none of the abovementioned materials are present – the equipment complies with the requirements of the RoHS Directive - 2011/65/EU.

When the biological organisms in the used face masks are exposed to deep UV light in the range of 200 nm to 300 nm it is absorbed by DNA, RNA, and proteins.

Absorption by proteins can lead to rupture of cell walls and death of the organism. Absorption by DNA or RNA (specifically by thymine bases) is known to cause inactivation of the DNA or RNA double helix strands through the formation of thymine dimers. If enough of these dimers are created in DNA, the DNA replication process is disrupted, and the cell cannot replicate.

The microbiological hazards are eliminated as a result.

Action required: Yes

Warning against hazardous waste must be affixed to the container.

Warning - Hazardous waste

Contact with non-disinfected face masks can result in contact with viruses and bacteria.

When emptying the equipment, the operator must ensure the following general instructions:

- Use of personal protective equipment

Safety gloves

Wear safety gloves when emptying the equipment.

Face mask

Use face mask when emptying equipment.

11. Connection to and interruption from power supply – A.6.12

Hazard and risk estimation
Inadequate means or inappropriate means of disconnection engenders hazards like exposed live parts.

Risk evaluation and reduction
The equipment is installed with a plug/socket for a flexible cable supply.

The interruption and/or the re-establishment after an interruption of the power supply to the equipment does not lead to dangerous situations.

Action required: No

12. Equipment design – A.7.2

Hazard and risk estimation

The equipment is not manufactured in the same way each time, which can cause an error production of the equipment and the user can get an electric shock.

Risk evaluation and reduction

The equipment is designed and constructed to be safe and reliable to prevent hazards arising, in particular so that:

a) it can withstand normal use in foreseeable environmental conditions, including electric, magnetic, and electromagnetic disturbances considered as relevant in the product EMC standard or generic EMC standard.
b) it can withstand reasonably foreseeable misuse.
c) errors in logic will not cause hazards.
d) interruptions or normal fluctuations in the power supply will not cause hazards.

To ensure the production quality of the equipment a quality management system is used, for the production hereof.

Action required: No

Appendix A – Conclusion

This appendix serves as a conclusion to the clause Risk estimation, evaluation, and reduction. All the below mentioned bullet points refers to the corresponding reference number in the risk analysis, which require an action to achieve conformity.

In numerical order – the following hazards require action:

Hazard 10:

Warning against hazardous waste must be affixed to the container.

When the abovementioned hazard has been brought into conformity and the manufacturer has fulfilled the remaining requirements listed in Annex III, Module A in the Low Voltage Directive, the equipment is ready to be put on the market.

Annex III of the Low Voltage Directive states the remaining tasks:

- ~~*ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;*~~
- *ensure that the technical documentation referred to in Annex III, section 2 where applicable, contain at least the following elements:*
  - *a) a general description of the electrical equipment.*
  - *b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.*
  - *c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment.*
  - *d) a list of the used harmonised standards.*
  - *e) results of design calculations made, examinations carried out, etc.; and*
  - *f) test reports.*
- *CE marking and EU declaration of conformity*
  - affix the CE marking
  - draw up a written EU declaration of conformity in accordance with Annex IV

Both the requirements for the instructions and the marking can be found in Appendix C – Marking and Information .

Appendix B - Information for risk assessment

The following information has been included to provide the reader with a basic understanding of the equipment, regulations, and standards applicable, experiences and ergonomic principles in accordance with EN ISO 12100 section 5.2.

Related to equipment description

The equipment subject for the risk assessment is recycling bin for disinfecting used face masks by using UV illumination. The functionality of the equipment is limited to the intended use.

User specifications

The intended users of the equipment are people in public institutions, e.g., at hospitals, clinics, and medical practices. It can be nondomestic area.

Equipment specifications

The following equipment specifications consists of primary components, functionality, and phases.

The equipment consists of:

- Recycle bin
- 2 pcs. Light fixture
- 2 pcs. UV light sources
- Timer
- Padlock

Functionality:

When the biological organisms in the used face masks are exposed to deep UV light in the range of 200 nm to 300 nm it is absorbed by DNA, RNA, and proteins.

Absorption by proteins can lead to rupture of cell walls and death of the organism. Absorption by DNA or RNA (specifically by thymine bases) is known to cause inactivation of the DNA or RNA double helix strands through the formation of thymine dimers. If enough of these dimers are created in DNA, the DNA replication process is disrupted, and the cell cannot replicate.

Related to regulations, standards, and other applicable documents

Applicable regulations

The equipment is subject to the Low Voltage Directive 2014/35/EU as the voltage for the equipment is above 50 Vac or 75 Vdc.

Relevant standards

STANDARD REFERENCE	STANDARD TITLE	TYPE
EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk reduction	A
EN 60598-1:2015	Luminaires - Part 1: General requirements and tests	C

Relevant technical specifications or safety data sheets

Test report-MICEZ-2007-031904-LVD

Test report-MICEZ-2007-031904-EMC

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Certificate: M.2020.206.C5150 & BCTCY2004000068C

Related to experience of use

For relevant information regarding:

1. any accident, incident, or malfunction history of the actual or similar equipment
2. the history of damage to health resulting, for example, from emissions (noise, vibration, dust, fumes, etc.), chemicals used, or materials processed by the equipment
3. the experience of users of similar equipment and, whenever practicable, an exchange of information with the potential users.

See the harmonized standards listed above.

Appendix C – Marking and Information requirements

Marking of equipment

All equipment must be marked visibly, legibly, and indelibly with the following minimum particulars:

- the business name and full address of the manufacturer and, where applicable, his authorised representative,
- designation of the equipment,
- the CE Marking (see Article 30 of Regulation (EC) No 765/2008),
- designation of series or type,
- serial number, if any,
- the year of construction, that is the year in which the manufacturing process is completed.
- Rated voltage, number of phases and frequency (if AC), and full-load current for each incoming supply.

It is prohibited to pre-date or post-date the equipment when affixing the CE marking.

A.9 Information requirements

a) The name of the manufacturer or supplier, or the brand name or trademark, shall be clearly printed on the electrical equipment or, where that is not practicable, on its packaging. If appropriate, there shall also be marking to identify the date and place of manufacture.

a) Information provided with the equipment shall also include instructions for safe installation (assembly), maintenance, cleaning, operation and storage.

b) Where risks remain despite all the measures adopted, or in the case of potential risks which are not evident, appropriate warnings shall be provided.

c) The essential characteristics, the recognition and observance of which will ensure that equipment will be used safely and in applications for which it was intended and for which it can reasonably be foreseen, shall be marked legibly and indelibly on the equipment or, if this is not possible, in the accompanying instructions for use.

d) Information provided either by marking or in the instructions for use which is essential for the safe use of the equipment shall be easily understandable by the intended user.

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