

該 非 判 定 書

作成責任者

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対象貨物・役務

Bioquell 製 過酸化水素蒸気発生器

Z-2 及び R-30

判定（2018.1.22 施行法令準拠）

輸出令別表第一の	1 項～15 項	対象外
同	16 項	該当
外為令別表の	1 項～15 項	対象外
同	16 項	対象外

判定理由

対象貨物は、過酸化水素の蒸気を発生・拡散させ、もって周囲環境の滅菌をする装置である。

輸出令について

対象貨物は、過酸化水素蒸気発生器であるが、これは輸出令別表第一に掲げられた物品ではない。よって、対象貨物は輸出令別表第一の 1 項から 15 項について対象外と判定する。

外為令について

対象貨物には、技術情報、データ、プログラムの類は付属しない。よって、外為令別表については、対象外と判定する。

添付資料

1. 項目別対比表（全 1 頁）
2. 対象貨物資料（全 4 頁）

輸出貿易管理令 別表第1 項目別対比表 (該非判定用) 6367

輸出令別表第1で明らかに規制されていない貨物用

貨物名:	過酸化水素蒸気発生器
メーカー名:	Bioquell
型及び銘柄:	Z-2 及び R-30

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2018.01.22施行行政省令等対応 (1 / 1)

輸出令別表第1 関連	判定欄 (いずれかにレ点)	貨物の内容・理由等
輸出令別表第1の1から15の項及び貨物等省令第1条から第14条に該当する貨物か？	☐ はい ☒ いいえ	

注意事項:

※判定欄で「はい」にチェックした場合は、関係する項目別対比表で、該非判定をすること。本シートは、使用できない。

※輸出令別表第1の1から15の項及び貨物等省令第1条から第14条に該当しない場合であっても、食品や木材等を除き、輸出令別表第3 (ホワイト国) 以外に輸出する場合は、キャッチオール規制 (用途・需要者) について確認すること。

作成責任者: (作成年月日: H30年11月19日)	
会社名	柚木行政書士事務所
所属・役職	行政書士・STC Associate
(フリガナ) 氏名	ユノキ イサム 柚木 勇
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6367

Bioquell | Z-2



- **Mobile hydrogen peroxide vapour (HPV) generator capable of 6-log bio-decontamination**
- **Suitable for large room/zone volumes up to 250m³ in a regulated GMP environment**
- **Easy to operate, fast bio-decontamination using unique parametric or timed cycles**

The Bioquell Z-2 is an easy to use mobile HPV generator. It is able to bio-decontaminate rooms/laboratories up to 250m³ in a GMP regulated environment using GAMP-compliant software. It also has a unique parametric cycle control, eliminating the need for gas cycle development studies in non-GMP facilities.

The Bioquell Z-2 provides enhanced HPV delivery and control via a simple touch panel interface. It is ideal for sterilising all surfaces within a room providing a 6-log reduction in environmental bioburden, the same standard used for validating steam sterilisers/autoclaves.

The Bioquell Z-2 is suitable for facility/area bio-decontamination in GMP and non-GMP cleanrooms, aseptic processing lines, biologic manufacturing plants, biomedical facilities and biosafety/biosecurity areas.

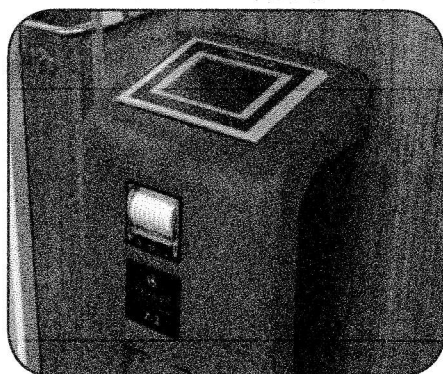


Image 1. Removable control lectern is placed outside of the target area during gassing

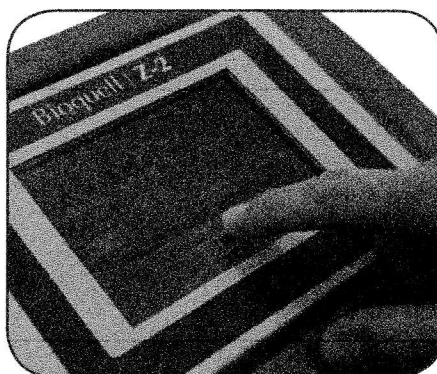


Image 2. Simple and easy to operate touch panel controls

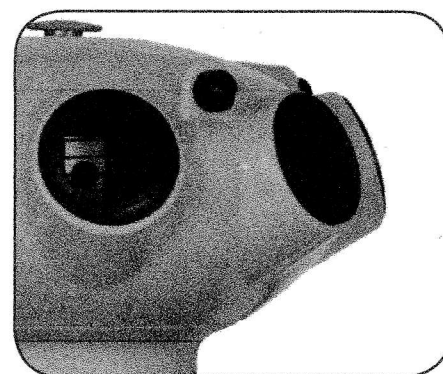


Image 3. Multi-directional nozzles for optimum vapour distribution

Technical specification

Physical and safety data

Dimensions (WxHxD)

With lectern 660 x 1444 x 710mm
(26.0 x 56.8 x 28.1in)
Without lectern 660 x 1444 x 560mm
(26.0 x 56.8 x 22.0in)

Weight

With lectern 95kg (209lbs)
Lectern 11.5kg (25lbs)

Operating data

Temperature

Operating 15-30°C or (59-86°F)
Storage 0-35°C or (32-95°F)

Relative humidity

Operating 80% RH (max)
Storage 80% RH (max non-condensing)

Temperature of vapour supply

50-70°C (122-158°F)

Maximum liquid volume

5L (1.32 US gallons)

Airflow rates

Vapour 50m³/hr (29.4CFM)
Air distribution 800m³/hr (471CFM)
Aeration 1000m³/hr (589CFM)

H₂O₂ liquid injection rate

230V 20g/min
120V/100V 10g/min

Power data

Power requirements

230V AC, 50/60Hz 13A
120V AC, 50/60Hz 12A
100V AC, 50/60Hz 15A

Power supply

Installation category II

Power consumption

230V AC, 3kW
120V AC, 1.4kW
100V AC, 1.5kW

Key features

The Bioquell Z-2 includes intuitive software with PLC (programmable logic controller) interfaced via a colour touch panel. With a 5L hydrogen peroxide solution capacity for continuous room gassing, it also includes an integral thermal paper printer. A hand held hydrogen peroxide gas sensor is provided. Volt-free contacts allow remote start/stop functionality and a lightweight detachable control panel is provided for operation outside the target room/zone. The Bioquell Z-2 utilises 30-35% w/w hydrogen peroxide solution, supplied in pre-filled 5L volumes.

Operation

After loading the Bioquell Z-2 with hydrogen peroxide solution, predetermined parameters or user determined cycles can be employed to bio-decontaminate the target area. A thermal printer allows for hard copy data recording of each stage of the cycle. A Bioquell aeration and distribution system is required for aeration in areas where room HVAC cannot be used.



Image 4. Bioquell's pre-filled hydrogen peroxide consumable offers optimal performance and safety.

Optional accessories include:

- Interface to Yokogawa Data Logger (21 CFR Part 11 compliant)
- Additional external aeration/catalyst unit, to reduce hydrogen peroxide vapour bio-decontamination cycle times further, can be linked.

Validation and service

Validatable compliant software.

Bioquell provides complete service including:

- Installation and integration
- Preventative maintenance plans
- Extensive field-based service engineer network
- IQ/OQ/PQ documentation and execution
- Bio-decontamination cycle development services

Your local distributor:

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Bioquell | R-30



- **Rapid removal of hydrogen peroxide vapour (HPV)**
- **Active distribution technology**
- **Mobile, lightweight & highly manoeuvrable**

The Bioquell R-30 is a high speed catalytic convertor developed to support a broad range of HPV-based bio-decontamination generators, used throughout the life sciences sector. Bioquell's HPV technology is used to eradicate microorganisms – comprising bacteria, viruses and fungi.

Bioquell's unique catalytic filters and air exchanger are a result of extensive research and development. The filter design maximises air volume throughput, resulting in rapid aeration (the longest part of the HPV bio-decontamination cycle). This is required to reduce the concentration of the HPV to a safe occupational exposure limit (OEL) of <1ppm, enabling a risk-free re-entry to the room.

The Bioquell R-30 also incorporates other features, including the use of a patented active HPV distribution system. This improves the distribution of the HPV during the bio-decontamination cycle, resulting in an excellent biological kill. The Bioquell R-30 has also been designed to be self-sterilising during each bio-decontamination, removing the risk of any location-to-location transfer of viable bioburden.



Image 1. Ergonomic design facilitates ease-of-use

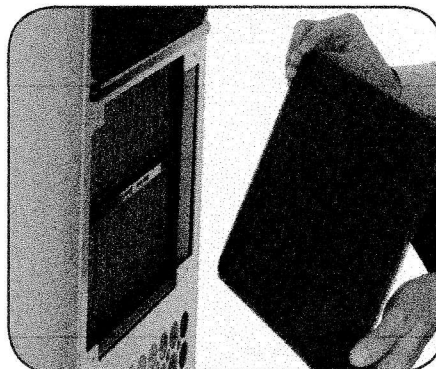


Image 2. Bioquell R-30 external pre-filter removed to reveal the hydrogen peroxide catalytic conversion filter

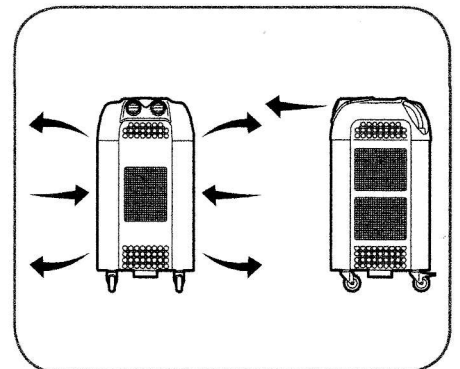


Image 3. Bioquell R-30 airflow dynamics achieve rapid aeration cycles

Physical and safety data

Dimensions (WxHxD)

638 x 1248 x 671mm (25.1 x 49.1 x 26.4in)

Unit weight

90kg (198lbs)

Operating data

Temperature

Operating 15-30°C (59-86°F)

Storage 0-35°C (32-95°F)

Relative humidity

Storage 80% RH (Max non-condensing)

Power data

Requirements

230V AC, single phase, 50/60Hz, 4.4A

120V AC, single phase, 50/60Hz, 8.1A

100V AC, single phase, 50/60Hz, 9.5A

Supply

Installation category II

Consumption

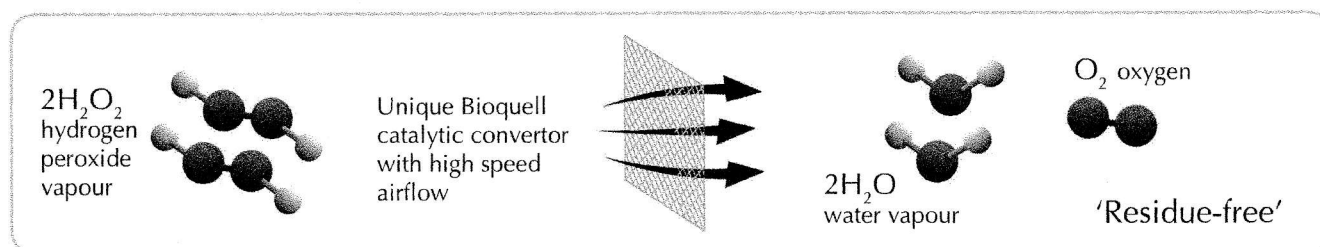
0.83kW (aeration mode) - all models

Key benefits

The Bioquell R-30 is a low maintenance unit, aiding fast and efficient bio-decontamination cycles. It quickly and efficiently converts HPV to residue-free, harmless water vapour and oxygen, leaving an environment that is safe to re-enter. The Bioquell R-30 is the latest generation catalytic converter which incorporates a proprietary filter that has been optimised for use with Bioquell's HPV technology.

Operation

Easy to operate, the Bioquell R-30 connects directly with the Bioquell range of HPV generators. Each stage of the HPV bio-decontamination cycle (including aeration) can be recorded on the generator and printed. The Bioquell R-30 aeration and distribution system assists HPV distribution and provides catalytic aeration to reduce cycle times.



Validation and service

Bioquell provides a complete service including:

- Installation
- IQ/OQ/PQ documentation and execution
- Bio-decontamination cycle development services
- Extensive field-based service engineer network
- Preventative maintenance plans

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