STERLINK *U-510*

User Manual

vetovation

Welcome

Thank you for purchasing STERLINK U510, a medical low temperature plasma sterilizer. Before using the product, please read the manual thoroughly with care.

Contents

1. How to Use the User Manual

- Before using the product, the user must read this Manual.
- The user must be aware of the product configuration and operation method before use.
- To operate the product, the user must have sufficient knowledge on product safety.
- Please keep the User Manual with due care to ensure that you can easily and quickly find the information needed in case any problem occurs.

※ This Manual is produced based on the current condition, and the details may be changed without prior notice.

2. Safety Information

Plasmapp considers user safety as the first priority and provides the information on how to use the product safely through this Chapter.
The user must read the safety information and instructions before using the product. Warnings, cautions and notes in the User Manual must be read and understood carefully.
This information ensures the safety of our customers and helps obtain the best results from our products.

	OFF (Power)	Disconnects from outlet and powers off
	ON (Power)	Connects to an outlet and powers on
	Warnings and Cautions	Specifies the conditions or circumstances that may cause physical injury or property damage
	WEEE (Electrical and electronic equipment waste disposal guidelines)	Specifies compliance with waste disposal guidelines

※ We are not liable for any accidents such as product damage due to using the product by methods other than those specified in this Manual.

Personal Safety & Emergency Measures

Warning! HYDROGEN PEROXIDE IS CORROSIVE.
Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always were latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following a cancelled cycle or error occurrence. Following hydrogen peroxide may be present.

Warning! HYDROGEN PEROXIDE IS AN OXIDIZER.
Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Concentrated hydrogen peroxide is a strong oxidizer and may react with organic materials, causing ignition and fire.

Warning! RISK OF EYE INJURY.
Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If there is a contact with eyes, immediately rinse eyes thoroughly with a large amount of water. Consult a physician immediately.

Warning! RISK OF SKIN INJURY.
Direct contact between the skin and hydrogen peroxide can cause severe irritation. If the contact occurs, immediately flush skin with large amounts of water. If symptoms are severe or persist, consult a physician immediately.

Warning! RISK OF RESPIRATORY IRRITATION.
Inhalation of hydrogen peroxide vapor may cause severe irritation to the lungs, throat, and nose. If inhaled, move to a location with fresh air for breathing. If your symptoms are severe or if they persist, contact your doctor immediately.

Warning! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC.
Ingestion of hydrogen peroxide may be life-threatening. If swallowed, drink plenty of water immediately to dilute. Do not try to induce vomiting. Please consult a doctor immediately if the symptoms are severe or persist.

Personal Protective Equipment

Warning! HYDROGEN PEROXIDE MAY BE PRESENT.
In case of process cancellation or error, always wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

Cautions, Warnings and Notes

Warnings and cautions are accompanied by symbols surrounded by a triangle and are printed in the text in boldface italics. Warnings indicate events or conditions that can result in serious injury or death. Cautions indicate events or conditions that can result in severe damage to the equipment.

Note are accompanied by a check mark and are printed in italics. Notes highlight specific information about the proper use and maintenance of the STERLINK U510 system.

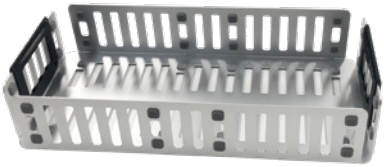
Symbols

	**Hot surface** | Do not touch without protective equipment.		
	**Dangerous chemicals** | Use personal protective equipment.		
	**Toxic chemicals** | Avoid exposure, contact and ingestion.		
	**Risk of hand injury** | Protect your hands carefully during the operation.		
	**Risk of electric shock** | There is a risk of electric shock if you touch it without an electrical safety device.		
	**Wearing PPE glove**		**Temperature limit**
	POWER ON		**Humidity limit**
	**POWER OFF**		**REFER TO INSTRUCTION MANUAL**
	**PROTECTIVE EARTH (GROUND)**		**NO PUSHING**
	**AC (Alternating current)**		**NO SITTING**
	**Manufacturer**		**NO STEPPING ON SURFACE**
	**Date of manufacturing**		**Consultation electronic instruction for use**
	**Use-by date**		**CAUTION**
	**Serial number**		

3. Product Configuration

Main unit of the product

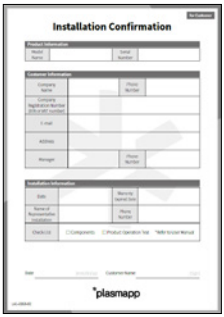
Power cable
(Provided by the Manufacturer)



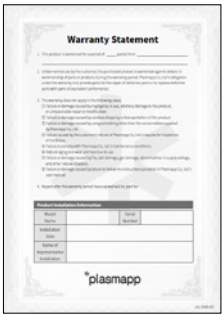
Tray

Sterilant cartridge

Quick Guide



Installation Confirmation



Warranty Statement

4. What Can be Sterilized

Items Not to be Processed

The following items should not be processed by the STERLINK U510 sterilization system.

- Single use items for which the manufacturer does not recommend re-use.
- Liquid and powders.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, buck towels, gauze sponges, or any item containing wood pulp.
- Paper instrument count sheets or lot stickers.
- Items with mated Nylon® surfaces.
- Instruments and devices that cannot withstand a vacuum and are labeled for gravity stream sterilization method only.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Dead-end lumens must not be processed.
- Other instruments for which the manufacturer has not specifically recommended sterilization in the STERLINK Sterilizer.

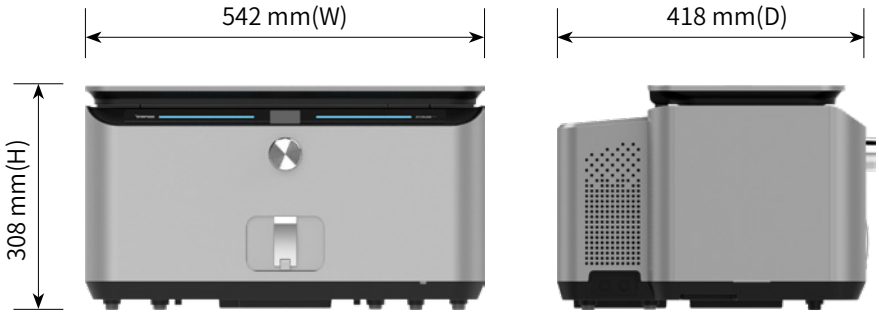
Caution! RISK OF DAMAGE TO THE LOAD OR STERILIZER.
Do not attempt to sterilize items or materials that do not comply with the guidelines specified in this User manual. Consult the medical device manufacturer's instructions or call your local Plasmapp customer support representative to determine whether an item can be sterilized by the STERLINK U510 sterilization system.

5. Product Description

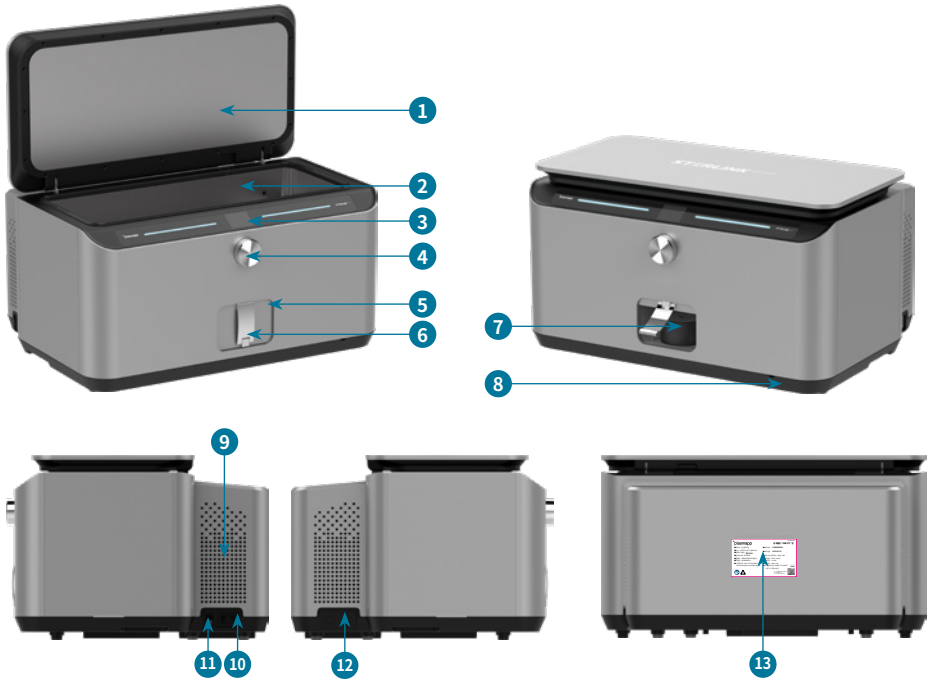
Purpose of Use

STERLINK U510's sterilization system is a low-temperature plasma sterilizer for inactivating microorganisms in the metal and non-metal medical instruments, including a wide range of surgical instruments, at low temperatures. It provides an effective, safe, fast, economical, easy-to-use, reliable and versatile method of sterilization.

Appearance and Dimensions



Width (W)	Depth (D)	Height (H)	Weight
542 mm	418 mm	308 mm	30 kg



①	Door	: Opening and closing device for introducing a sterilized object into the chamber
②	Chamber	: A space to sterilize the input sterilization target
③	LED, LCD display	: Monitoring the progress
④	Dial	: Control with configurable actions
⑤	Sterilant cartridge compartment	: A space to store exclusive Sterilant cartridge
⑥	Door Handle	: Handle for opening and closing cartridge
⑦	Sterilant cartridge	: Exclusive Sterilant cartridge
⑧	USB C Type Port	: Available only to administrators or users with service-level access.
⑨	Vent	: The heat generated during operation is discharged to the outside of the device.
⑩	AC Inlet	: Power cable connector
⑪	Power switch	: Switch for turning the power on and off
⑫	Fuse	: Safety device
⑬	Product label	: The label for displaying information such as serial number

Product Specifications

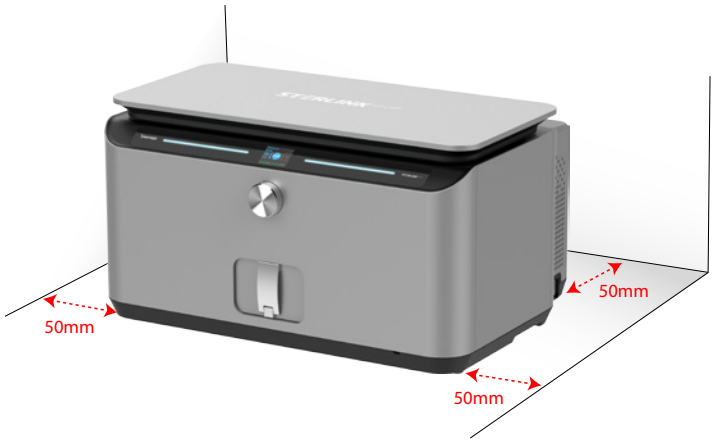
Classification	Details			Unit
Measurement	542 (W) × 418 (D) × 308 (H)			mm
Chamber capacity	470 (W) × 185 (D) × 90 (H), 8			mm, ℓ
Product weight	30			kg
Safety device	Physical	Prevention of opening by door sensor and vacuum		-
	Electrical	Insertion of rated fuse for overcurrent protection		-
Electrical characteristics	Rated voltage	100 ~ 120		VAC
	Rated frequency	50 / 60		Hz
	Power consumption	1.7		kVA
	Fuse	125V, 15A		-
Sterilization process time	Sterilization performance	Standard Mode	Lumen 0.7*150	mm
		Advanced Mode	Lumen 0.7*500	
	Sterilization time	Standard Mode	17 ± 2	min
		Advanced Mode	24 ± 2	
Sterilant	Hydrogen Peroxide (H_2O_2 58.0%~59.5%)			-

6. How to Use the Product

Check the before Start

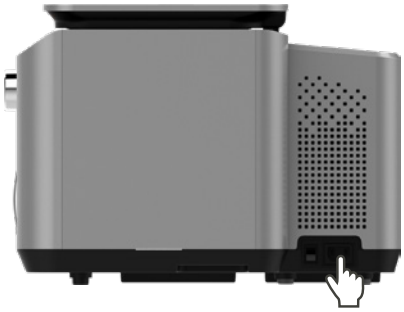
- Check the Cautions and How to Operate before using this product.
- You must use the equipment after familiarizing yourself with the User Manual.
- Do not supply a voltage not specified in the product specifications to the sterilizer.
- If you need to use unspecified power for urgent sterilization under special circumstances, you must contact the nearest agency or head office, and if any product damage occurs due to the use of unspecified voltage, the product warranty will not be provided.
- To preheat the sterilization chamber before starting the sterilization process, you must turn the power switch on after connecting the power cord 15 minutes in advance. Starting the sterilization process without preheating may result in sterilization failure.
- This equipment is used by placing it in a designated place.
- There should be at least 5cm space behind and around the sides of the equipment, and it shall be placed on a flat surface (within 3 degrees).
- Do not use it within a close proximity to the equipment that generates a lot of electromagnetic waves.
- Do not install in a place where fire or steam is generated.

Installation & Operation Environment

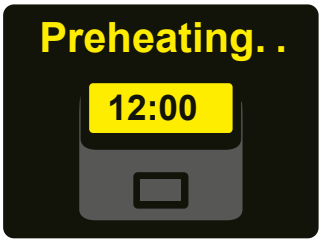


Operating Range	Spec Range
Service Clearances	Back ≥ 50mm
	Right Side ≥ 50mm
	Left Side ≥ 50mm
Operation Temperature	5 ~ 40°C
Operation Humidity	30% – 85%
Altitude	≤ 2000m
Using Place	Indoor use
Pollution Degree	2

Start and Preheating



1 Turn on the power switch on the side of the sterilizer.



* Automatically changes to the Ready screen display when count down is completed.

2 When the power is turned on, the preheating proceeds automatically.
※ It takes about 15 minutes and may vary depending on the installation environment.

※ The screen below is displayed on the LCD and you can check the preheating progress.

Sterilant cartridge' Lead-in

1 Lower the sterilant compartment cover on the front of the product

2 Hold the door handle and lift it up to open the compartment.

3 Load the sterilant cartridge by sliding them into the open compartment.
※ Push it in until it clicks into position.

4 After checking that the Sterilant cartridge is loaded in the correct position, close the compartment by pulling handle down
※ Error will occur if it is not closed all the way.

Sterilant cartridge' Lead-out

1. Lower the sterilant compartment cover on the front of the product

2. Hold the door handle and lift it up to open the compartment

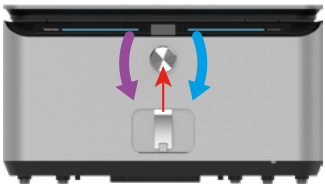
3. Pull out the sterilant cartridge.

4. After the sterilant cartridge is unloaded, close the compartment by pulling handle down.

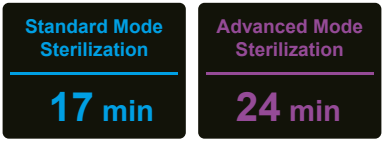
5. When a Cartridge is empty, dispose of the used cartridge according to your health care facility's policy.

Sterilization

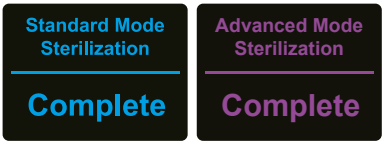
1 Hold the door, open it, and load the object to be sterilized.



2 After loading, close the door and turn the dial to select the desired sterilization process.



3 Press the dial to perform the sterilization process.



* The sterilization execution screen for each selected mode and the screen displayed after the sterilization is completed.
(Remaining time is shown)

4 When the sterilization process is completed and the 'Complete' screen is displayed, open the door and retrieve the object.

※ After operation, rest for 10 minutes before reuse.

Precautions for Use

- Do not touch the door while in use.
- Do not turn off the power while in use.
- Do not move the product while in use.
- Do not remove the power cable while in use.
- Do not lean on the product.
- Do not touch the device with wet hands while it is in operation.
- Make sure that the object is dry before inserting it into the product.
- Do not dismantle the product arbitrarily.
- Do not apply any shock to the product.
- Be careful not to introduce foreign substances into the device.
- The loads should be processed with Tyvek® pouches.
- Use only the same cable as part 3 Power Cable SPAC
- Using the BI(Biological Indicator) is an important indicator to confirm the sterilization performance of the sterilization process. To check the performance of the sterilization process, seal the specified BI with the Tyvek® pouch, place it in the chamber, and perform the sterilization process. After the sterilization process, check whether the BI is sterilized. It is recommended that this biological test be performed once a week, or in accordance with your facility's policy.
- Using the CI(Chemical Indicator) is one way to ensure that the sterilized medical device has been exposed to the specified process. Place the specified CI inside the Tyvek® pouch with the medical device. After the sterilization process is completed, check if the CI color has changed as mentioned by the manufacturer. If the CI has changed color correctly, it means that the sterilized medical device has been properly exposed to the specified sterilization process.

Warning! ELECTRIC SHOCK HAZARD
To avoid the risk of electric shock, this product must only be connected to a power supply with protective ground.

Warning! INSTALLATION POSITION
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Caution! CHECK EXPIRY DATE.
Before using the sterilant cartridge, check the expiry date. If the cartridge is expired, do not use. Dispose of the expired cartridge and use an available unexpired sterilant cartridge.

Warning! DO NOT USE IT IF PACKAGING IS DAMAGED.
Do not use if the package has been damaged or has not been properly sealed. If the sealing is not perfect, it's difficult to have confidence of asepsis.

Warning! ELECTROMAGNETIC DISTURBANCES.
A high voltage is used at the start of the sterilization cycle, which may cause minor disturbances to electronic devices outside the product. Also, portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in sterilization failure.
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Caution! KNOW WHAT YOU CAN PROCESS
Before processing items in the sterilizer, make sure you know how the STERLINK U510 sterilization process will affect the items. If you have questions, or if you are in doubt about the materials in your device, contact the medical device manufacturer or your local Plasmapp customer support representative for more information.

Caution! RISK OF WARRANTY VIOLATION
Improper processing may limit liability for damage to processed instruments. The manufacturer cannot warrant the damage of the instruments due to improper use.

Caution! BE CAREFUL! MAY BE CHAMBER HOT!
The temperature in the chamber may be very high. Therefore, when working in the chamber, be sure to wear protective gloves, and be careful of burns.

Warning! USE OF ACCESSORY & CABLE.
Use of accessories, cables other than those specified or provided by the manufacturer of this equipment could result in decreased electromagnetic compatibility of this equipment and result in improper operation.

Warning! DISPOSAL OF HYDROGEN PEROXIDE
Hydrogen peroxide is designated as dangerous and hazardous medical wastes by American environment protection association and shall be disposed in accordance with the local regulation. (US waste disposal regulation: U.S. EPA 40 CFR 262)

Caution! HAND CRUSH HAZARD
The door of the sterilizer is designed to be manually opened and closed, and your hand can be injured by the door. Keep hands clear when opening or closing the door.

Warning! POSSIBLE NON-STERILE DEVICE.
Improper loading of the cartridge may result in either a non-sterile device or cycle cancellation. The cartridge should be precisely loaded on the cartridge holder of the sterilizer and sliding door should be closed properly.

Caution! PRODUCT MANAGER ACCESS AUTHORIZATION.
Additional utility functions, including the software update function that can be used by connecting a PC to the product via a USB port, can only be used by the administrator of the company selling this sterilizer.

Caution! HYDROGEN PEROXIDE MAY BE PRESENT.
Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

7. How to Manage After Use

How to Clean

Do not use organic solvents other than aqueous alcohol for exterior and interior cleaning.

- If there is dust, lightly wipe the contaminated area with a wet tissue.
- If the stain is severe or cannot be removed with a wet wipe, use a cleaning sponge with water and wipe off any remaining stains with a cleaning wipe or soft cloth.
- If foreign substances including oil are present, spray disinfectant ethanol on the contaminated area and wipe off the remaining stain with a cleaning wipe or soft cloth.
- In the case of crayons and colored pencils, wipe by gently rubbing the contaminated area with a clean eraser.

※ Cautions

Clean only when the machine is turned off.

Do not use cleaners containing sodium hypochlorite-based or chlorine-based solutions.

Do not use ketone substances and substances such as acetone, ethyl alcohol, toluene, methyl acid or methyl chloride.

How to Store

The place where the product is stored must meet the following criteria.

- The product must be stored in a place with sufficient area and space, taking into account the movement and flow of people using the product.
- Store the product so that the bottom surface does not touch the ground.
- Unpacking Instructions
  - When unpacking the product, it is crucial to do so in an area with a flat and stable surface.
- Place the product box in a manner that prevents any impact or shock during the unpacking process.

Do not drop or apply excessive force to the product when storing it.

Store in a place that is not adversely affected by temperature/heat, humidity/water, air pressure, sunlight, dust, salt/ion/organic solvent/ harmful chemicals, vibration/shock, etc.

- The product should be stored in a well-ventilated place with suitable lighting.
  - Brightness or lighting must be sufficient for work
  - Install curtains or blinds on windows that face direct sunlight
  - Ventilation is closely related to the quality of products and the hygiene of users, therefore air conditioning facilities shall be used as necessary
- The storage area must be equipped with insect repellent, anti-corrosive and fire extinguishing facilities.
  - Install traps in drains, seal passages through walls, install insect screens in exhaust/ventilation vents, etc.
- between -30 °C and 50 °C, and the humidity must be maintained lower than 90 %.
- When the product is moved from its initial installation location to another place, the location must be changed by a professional engineer recognized by the sales agent.

How to Handle and Distribute

Pay attention to the following items to prevent product damages and quality problems caused by negligence in the process of handling and distributing the product.

- Avoid direct sunlight during handling and distribution.
- Pay attention to safety conditions such as inclination, vibration, and shock.
- Avoid the places where chemicals are stored or where gas is generated.
- Load with the direction of the arrow printed on the packaging box facing upward.
- In the distribution process, loading more than 4 layers is prohibited. (Possible to stack up to 3 layers)
- Do not use hooks when moving products or packaging boxes.
- The products or packaging boxes are should be carried out by wagon has more than 600 x 400 size.

※ It is specified that we are not responsible for any and all accidents that occur while using the product by methods other than specified in the Manual.

8. How to Take Action in the Event of Problems

- Please refer to How to Take Action for the phenomenon below.
- If the phenomenon is not resolved or happens repeatedly, contact the manufacturer.

Phenomenon		Description	How to Take Action
⚠ Caution Description	**Caution**	Empty Cartridge	· Replace cartridge
		Expired Cartridge	· Replace cartridge
		shutdown occurred during process	· Restart after checking the power cable · Call service center in case of recurrence
		Emergency stop (When Purification process is completed)	· Restart the process
		sliding door was opened (When Purification process is completed)	· Restart after confirming that the cartridge door is closed. · Call service center in case of recurrence
		chamber door was opened (When Purification process is completed)	· Restart after confirming that the chamber door is closed. · Call service center in case of recurrence
⚠ Code XX Description	**Code. 10**	Rebooting or contact service center	· Restart the process · Call service center in case of recurrence
	Code. 20	Base pressure issue (When Purification process is completed)	· Restart the process after removing moisture and oil from the chamber and sterilization object. · Call service center in case of recurrence
	Code. 21	Diffusion pressure issue (When Purification process is completed)	· Restart after checking the cartridge status
	Code. 30	Invalid cartridge	· Replace cartridge

9. EMC Compliance Information

Emission and Immunity examination

STERLINK U510 complies with the following standards.

- EMC test method used : EN 55011:2016+A1:2017
  *EN55011:2016/A2:2021
  (CISPR11:2015+A1:2016+A2:2019)
  EN60601-1-2:2015+A1:2021(IEC60601-1-2:2014+A1:2020)
  EN IEC61000-3-2:2019*IEC61000-3-2:2018)
  EN61000-3-3:2013(IEC61000-3-3:2013)

- Immunity test levels and emissions compliance class and group
  · Class A / Group 1

- Deviation from collateral standard and allowances used : N/A

STERLINK U-510

※ We are not responsible for any accidents such as product damage caused by use other than those specified in this manual.

Manufacturer

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STERLINK U-510

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