ELETRA SMART

Intraoral Digital Impression Instrument **Product Specification**

CE

CONTENTS


ELETRA
SMART

1. General Information

CAUTION

Be sure to observe all warnings!
Please adhere to all safety information and warnings to prevent personal injury, material damage, or damage to your Intraoral Digital Impression Instrument. Safety information and warnings are highlighted in this specification using the words “WARNING” and “CAUTION.”

The symbols used in this document imply the following:

WARNING

Warnings regarding situations where there is a risk of injury to individuals if the information is not observed.

CAUTION

Caution addressing hazards such as loss of data, invalidation of warranties or service contracts, risk of property damage, and damage to the Intraoral Digital Impression Instrument that may occur if the information is not observed.

2. Product Information

Product Name	Intraoral Digital Impression Instrument
Model	ELETRA SMART
Classification	Neither class I nor class II equipment, DC 5V supplied by computer through USB. The APPLIED PARTS is classified as TYPE B. IPX0.

3. Product Components

The product consists of the probe, the probe bracket, the calibrator, the scanner head, and the supporting software.
The scanner head is applied part. The structure of ELETRA SMART is shown Figure 1 below.

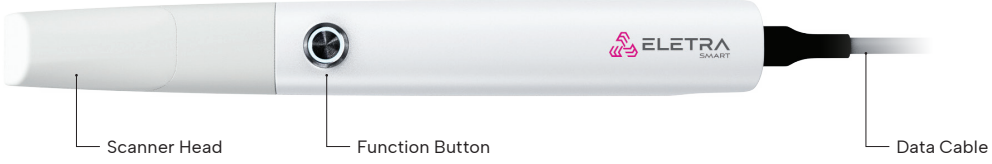


Fig1. Structure of ELETRA SMART

4. Dimension

Total Size	221mm (L) x 27mm (W) x 25mm (H)
Size of Scanner Head	83mm (L) x 19 mm(W) x 14mm (H) Window: 18mm x 16mm

5. Intended Use and Contraindication

5.1 Intended Use

This product utilizes the optical scanning method to acquire three-dimensional shape feature data of the surfaces of teeth, gums, and other tissues. It outputs three-dimensional digital impression data that can be utilized in CAD/CAM denture design and processing.

WARNING

The unintended use of the Intraoral Digital Impression Instrument can lead to physical injury to patients and operators, as well as damage to the product.

5.2 Users

Dental professionals such as trained physicians, physician assistants, technicians, etc.

5.3 Contraindication

Patients with the following contraindications are not suitable for intraoral digital impressions. These contraindications include but are not limited to:

1. Patients have oral mucosal disease; patients have mental illness; patients have Parkinson's disease; patients have ADHD (Attention Deficit and Hyperactivity Disorder); patients have epilepsy.
2. Spray optical shading powder on smoked areas when patients have very severe black smoke stains that are not conducive to optical scanning. If the special shading powder need to be sprayed, these diseases need to avoid dust are contraindications, mainly including Not limited to: allergic or multi-drug allergic; severe respiratory diseases, asthma patients, etc.
3. It should not be used on patients who have or have had photobiological reactions (including those with excessive sun exposure or porphyria) or who have been treated with photosensitive drugs (including methoxsalen or chlortetracycline).

6. Environmental Requirements

Operating Conditions

Temperature	5ºC ~ 30ºC
Relative Humidity	≤ 80%
Atmospheric Pressure	700hPa~ 1060hPa
Operating Environment	Home healthcare environment and professional healthcare facility environment. Indoor operation, prevent direct sunlight and strong lights, and keep away from electromagnetic sources, cold and heat sources, and vibration sources.

Transport Conditions

Temperature	-10ºC ~ 55ºC
Humidity	≤ 93%
Atmospheric Pressure	700hPa ~ 1060hPa

Storage Conditions

Temperature	-10ºC~55ºC Relative Humidity ≤ 93%
Atmospheric Pressure	700hPa ~ 1060hPa Well-ventilated, non-corrosive gas chamber. Prevent moisture, corrosion and avoid direct sunlight.

7. Working Power Requirements

Powered by USB3.0 port of computer: 5V, 0.9A

8. Safety Information

8.1 Prerequisites

CAUTION

Please read all instructions carefully, including all warnings and cautions. It is essential to comply with the warnings in the specification in order to prevent injury to individuals and damage to the Intraoral Digital Impression Instrument (referred to as the device hereinafter). The proper functionality and safety of the device can only be ensured if the safety precautions outlined in this specification and on the device are observed.

CAUTION

Please examine the device for any mechanical damage on:

- All enclosures
- All cables

Safety can only be guaranteed if there is no damage observed on the device.

Modification of the Device:

WARNING

No modification of this device is allowed.

Approved Software Only:

CAUTION

To ensure the runtime reliability of the device and its programs, only install approved software to prevent interference.

Proper Training:

CAUTION

Before attempting to use the device with patients, please ensure the following:

- You have received appropriate training on how to use the device, or you have read and understood all sections of this specification that describe correct operation.
- You are thoroughly familiar with the safe operation of the device as described in this documentation.

In Case of Device Failure:

WARNING

If the device malfunctions at any time, or if you suspect that it is not working correctly in any way, please follow these steps:

- Remove the device from contact with the patient.
- Unplug the probe and ensure it cannot be used until it has been checked.
- Contact your reseller.
- DO NOT attempt to open any covers on the device.

8.2 Mechanical Hazards

Dropped or Damaged Device:

WARNING

If you accidentally drop a scanner head on the floor, it is imperative that you dispose of it immediately and refrain from using the same scanner head again for scanning. There is a high risk that the mirror inside the scanner head may have become dislodged and could potentially fall out.

CAUTION

If the probe body is dropped or bumped, it should be calibrated immediately before any further use. If calibration fails, please contact your technical service provider. Refer to the instructions on calibrating the device for further guidance.

8.3 Explosion Hazards

Environment:

WARNING

The product is not intended for use in potentially explosive environments, such as in close proximity to flammable liquids or gases, or in oxygen-enriched atmospheres.

8.4 Electrical Safety

The Power Interface:

CAUTION

The device should only be connected to the USB interface of UL/CSA 60950-1 certified computer equipment. If the data cable used for power supply needs to be replaced, please contact the manufacturer. Do not attempt to replace it yourself.

Electrical Shock:

WARNING

There is a risk of electrical shock if you attempt to access the inside of any part of the device. Only authorized and qualified service personnel are allowed to access the inside of any part of the device.

Stress on Cables:

CAUTION

All externally connected cables must never be subjected to pulling stress.

Spilled Liquids:

WARNING

Do not bring liquids such as beverages near the device.

Do not spill liquids on the device.

Disconnected from the Power Supply:

WARNING

There is no power ON/OFF switch on the device. Therefore, the only reliable method to disconnect the device from the power supply is by unplugging the data cable. It is important not to position the device in a way that makes it difficult to unplug the data cable.

8.5 Eye Safety

Visible Laser:

WARNING

Do not look directly into the visible laser beam during use, and ensure that the beam from the scan window (laser window) does not directly hit the eyes of the operator or the patient.

The laser wavelengths used by the product are 450nm and 520nm, which is a class 1 laser product. The repetition frequency is 15Hz, and the maximum power was 32.5µW at 450nm and 12.3µW at 520nm.

WARNING

The device emits white light from the scanner head during operation. The device is compliant with EN(IEC)62471 (Photobiological safety of lamp and lamp systems). However, we advise caution when handling the device.

A brief glimpse of the light into the eye is not dangerous. However, it is important not to gaze directly at the beam or view it directly with optical device. Additionally, avoid aiming the beam towards other people's eyes.

8.6 Cautions

This product is an optical scanning device. During its use, it should not be subjected to vigorous collisions. Please handle the calibrator in the product with care, as any stains on it can degrade the product's performance.

While this product meets the requirements for electromagnetic compatibility of medical devices during use, it is not recommended to use it in environments with strong magnetic fields, strong switches, or strong light sources. Such environments may potentially affect the performance of the product.

For connectivity, this product can only be connected to the USB port of a computer device that is UL/CSA 60950-1 certified.

When the product reaches the end of its life, it should be disposed of in accordance with local laws and regulations. Alternatively, you can contact the manufacturer for recycling and centralized disposal, following local laws and regulations.

9. Product Hardware Installation Instructions

This product is a precise optical equipment. Manufacturers and distributors shall not be held liable for any loss of product safety, reliability, and performance if the operator does not operate the product in accordance with the instructions or uses it in a manner that leads to collisions or falls due to improper use. In the event of a fall, please check the product's functionality and calibrate it using a calibrator. If the calibration fails, please contact the manufacturer for repair.

When the probe is not in use, it should be placed on the probe bracket and positioned on a horizontal operating table to prevent any damage from improper placement that may result from falling.

Installation Steps:

1. Connect the data cable to the computer's USB port and ensure that the function button is illuminated.
2. Launch the scanning software and follow the scanning operation requirements. During the scanning process, light will be projected from the scanning window.
3. After completing the scanning, unplug the data cable to disconnect the device.

Note: When the device is operational, the power consumption of the heating element on the scanning head is 0.35W.

10. Product Software Description

10.1 Software Operation Configuration Requirements

This product can only be used by installing software on the computer. The requirement for the recommended configuration of computer hardware is no less than the following configuration:

CPU	Intel i7-12700H / Intel i7-11800H or above
RAM	16G / 32G
Hard disk	SSD 512G or above
GPU	RTX2060 / RTX3060 or above
Operating system	Windows10 / 11 64bit

10.2 Software Basic Information

Software Name	ELETRA Cloud
Software Security Level	A

Network security: User access control provides the option to use a username and password for identity authentication. The user type is an ordinary user. Ordinary users have regular access to the device, allowing them to use it normally and view data results. The login interface is shown Figure 2 below.

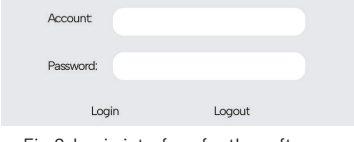


Fig 2. Login interface for the software

Data Saving Format: Standard STL, PLY format and PTY format defined by ELETRA.

10.3 Main Software Interface

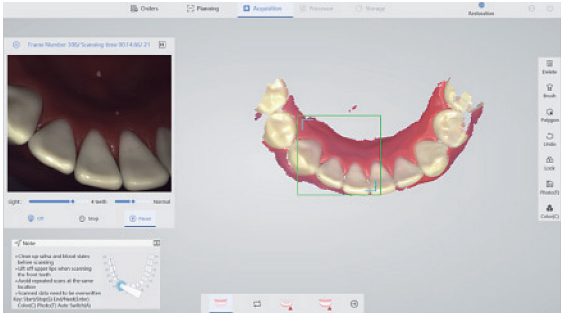


Fig 3. Main interface for the software

Please contact our local sales representatives for training materials.

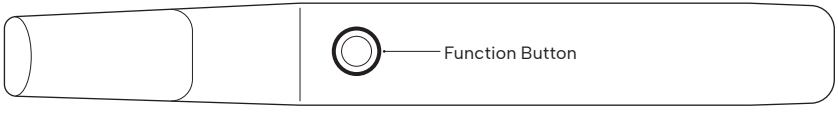
11. Application Method

11.1 Operating Steps

Please follow the instructions for Product Hardware Installation provided on page 14.

Once the startup process is complete, open the software and proceed with the scanning.

To initiate the machine, click the power-on button. After startup, click the scanning button to begin the scanning process. Click the button again to pause scanning. Double-click the button to switch the color of the data model. To end the scanning, press and hold the button for three seconds.



11.2 Scan Technique

Hold the probe body in the same way as a pen while scanning, Due to the limitation of the actual space in the mouth, it is necessary to ensure that the head window of the probe is as close to the tooth surface as possible (it is recommended to keep it within 2mm) for scanning, and the operation mode of suddenly far and suddenly near should be avoided.

Axial drag of the probe was the main scanning method, and radial drag of the probe was used in the scanning of the front teeth and occlusion points. Start scanning from the end teeth, first scan the occlusal data, then scan part of the buccal and lingual data, and drag from occlusal to mesial to scan the next tooth and follow the same operation to complete the frame scan of the posterior tooth area.

When entering the lingual surface of the anterior tooth area, drag the probe radial direction left and right to scan the lingual surface and incisal data, and then scan part of the labial surf ace data after the lingual surface is completed.

11.3 Calibration

According to the usage, it is recommended to use the calibrator to calibrate the product once a week. The product has not been used for three months; it is recommended to calibrate before use. When the device is impacted, or the product is moved or vibrated greatly, or to maintain the accuracy of the scanning accuracy, the scanner needs to be calibrated. Refer to “Software Operation Manual” for the calibration method.

CAUTION

The calibrator of the product should be properly kept. Once the calibrator is defaced, the performance of the product will be degraded.

12. Care and Maintenance Methods

The product is not expected to have long and frequent oral contact with patients. The scanner head must be cleaned and sterilized between patients to avoid cross contamination. It is recommended to sterilize the scanner head by means of moist heat steam sterilization (121 ºC, 15 min or 134 ºC, 6 min).

WARNING

To ensure the normal performance of the product, it is recommended that the times of repeated sterilization of the scanner head shall not more than 50.

The scanner head should be replaced when the appearance is damaged or sterilized 50 times. The scanner head can be purchased separately from the seller or manufacturer.

Recommended Sterilization Method:

- Clean the scanner head with soapy water and a soft brush, then place it under running water for rinsing.
- Wipe the water stain on the surface of the scanner head with medical gauze and wipe it thoroughly with ethyl alcohol. Pay special attention to whether there are stains or water stains on the head mirror. If there is, use another medical gauze to draw the ethyl alcohol and carefully wipe the head mirror. The sample was allowed to stand for two minutes after wiping.
- Place the scanner head which had been cleaned into 90 x 260mm self-sealing sterilization pouch (Materials: Medical high-temperature dialysis paper and medical CPP/PET complex film) and seal the sterilization pouch. Then place the packaged scanner head into sterilizing device tray.
- Place the sterilizing device tray into a small pressure steam sterilizer and set the sterilization parameters according to the instructions of the small steam sterilizer: temperature 121 ºC, 15 min, or temperature 134 ºC, 6 minutes.
- Keep the surface of the product clean. If the probe head reflective glass smudging, can dipping a small amount of ethyl alcohol with skimmed cotton, from the center to gently wipe the rotation. If the glass is scratched, it needs to be replaced.

During equipment usage, software errors and warnings can often be resolved through self-healing mechanisms implemented in the software. In the case of more serious problems, it may be necessary to shut down the software and then restart it. For general hardware errors, power cycling the equipment by turning off the power and then turning it back on can often restore normal operation. If a problem persists and cannot be resolved, it is advisable to contact the manufacturer or the seller for further assistance.

The maintenance personnel must take laser protective measures during the inspection process, such as wearing goggles.

WARNING

During the inspection, ensure that there is no person in the direction of laser irradiation.

Replacement equipment parts must be obtained from the manufacturer or manufacturer approved dealer.

CAUTION

The parts not supplied by the manufacturer may reduce the accuracy and safety of the equipment.

Disclaimer: We can provide the necessary information for equipment maintenance to the users with corresponding maintenance qualifications.

CAUTION

The device should not be serviced or maintained while in use with a patient.

13. Service Life

Expected service life: 8 years.

CAUTION

Over the period of use, the main electronic and optical components of the product may degrade, which can result in a reduction in product performance.

14. Parts List

Probe	x 1
Probe bracket	x 1
Calibrator	x 1
Calibrator cable	x 1
Scanner head	x 6
Protective case	x 1

15. Legend of Labels and Symbols

Caution

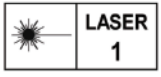
General Warning

Type B Application Part

Refer to instruction manual/ booklet

EU Authorized Representative

Serial Number



Laser Categories and Warnings

Humidity Limitation

Atmospheric Pressure Limitation

Temperature Limit

Manufacturer Information

Date of Manufacture

Medical Device

Function Button

Indicates a medical device that needs to be protected from moisture.

CE marking in conformity with Regulation (EU) 2017/745

The device should be sent to the special agencies according to local regulations for separate collection after its useful life.

16. Liability of the Manufacturer

The installation, adjustment, modification, and repair of this product are performed by persons or organizations approved by the manufacturer or distributor. The manufacturer must be able to ensure the safety of the product in accordance with the electrical, environmental, storage, maintenance, and operation requirements of the manual. Responsibility for reliability and performance.

17. About EMC Descriptions and Risk Warning

This product has passed the electromagnetic compatibility test and meets the requirements of 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.

The following application requirements shall be strictly observed during use, otherwise it may cause electromagnetic interference to other devices or reduce the anti-electromagnetic interference capability of the therapeutic device, or even lose the basic performance. This product belongs to the Group 1 Class B equipment specified in IEC/CISPR 11, non-permanent installation equipment, non-living support equipment, and belongs to equipment that is expected to be directly connected to the public power grid.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the product including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The cable information of this product is as shown in the following table. If there is a fault in the connection cable, please contact our company for maintenance or replacement. Otherwise, it may cause excessive electromagnetic interference. If there is something wrong with this product, please contact ELETRA promptly. Do not repair or replace the components yourself, or it may cause excessive electromagnetic interference.

No.	Name	Cable length (m)	Shield
1	Data cable	1.85	Yes
1	Data cable of calibrator	0.5	Yes

WARNING

The use of accessories or cables outside of the regulations together with equipment and systems may result in increased emissions or reduced immunity of the equipment or system.

WARNING

This product should not be used near or stacked with other devices. If it must be used close to or stacked, it should be observed and verified to work properly under its configuration.

Pass and Fail Criteria:

During and after the immunity tests, each function worked as intended, such as parameter, as per IFU.

Work Mode:

Scanning mode and calibrating mode.

Trouble Shooting

Issue	Solutions
No image display in 2D image area	• Make sure the device's USB interface is properly connected to the computer's USB 3.0 interface. • Restart the software and scanning device to check if the image can be displayed normally.
2D image flicker	• Check if the modulator is connected properly. • Replace the USB port of the de vice with the computer. • Connect your computer to the Internet.
Scans are easily interrupted and not smooth	• Inappropriate scan brightness. For plaster model scanning, choose 1/2, for resin model scanning, choose 3, for the intraoral scanning, choose 4, 5 is suitable for patients with darker teeth in the mouth. • During scanning, confirm that A above the image area is blue. If it is black, use keyboard A key to switch. • Standardize scanning methods. Ensure coverage of scanned data with existing data.
Out-sync of data between 2D and 3D	• Confirm whether the computer configuration meets the requirements (higher than or equal to our recommended configuration). • Delays caused by too many scans (single jaw scans should be completed within 3 minutes). • Uninstall antivirus software or add scanning software to the whitelist of antivirus software. • Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software.

Trouble Shooting

Issue	Solutions
Difficulty for scan relocation	• Ensure that the scanning direction is consistent with the previous scanning when repositioning. • Avoid long scans.
No 3D data when scanning	• Recalibration
Abnormal interrupt during scanning	• Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software. • Check whether the remaining storage space of drive C is sufficient. • Turn off or uninstall anti-virus software.

This product declares compliance with the contents of Table 1, Table 2, Table 3, and Table 4.

Table 1

Manufacturer's Declaration – Electromagnetic Emissions

The product is intended for use in the electromagnetic environment specified below. The users should ensure that it is used in such an environment.

Emission Measurement	Conformity
RF Emission CISPR 11	Group 1
RF Emission CISPR 11	Class B
Harmonic Emission IEC 61000-3-2	Not applicable
Voltage Fluctuations / Flicker emission IEC 61000-3-3	Not applicable

Table 2

Manufacturer's Declaration – Electromagnetic Immunity

The product is intended for use in the electromagnetic environment specified below. The users should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level Guidelines	Compliance Level
electrostatic discharge IEC 61000-4-2	Contact: ± 8 kV. Air: ± 2kV, ±4kV, ±8kV, ± 15 kV	Contact: ± 8 kV. Air: ± 2kV, ±4kV, ±8kV, ± 15 kV.
Radiated RF EM fields IEC 61000-4-3	3 V/m 80MHz – 2, 7 GHz 80% AM at 1 kHz	3 V/m 80MHz – 2, 7 GHz 80 % AM at 1 kHz
Electrical fast transient burst IEC 61000-4-4	± 2 kV f or power supply lines.	N/A
Surge IEC 61000-4-5	± 1 kV line(s) to line(s). ± 2 kV line(s) to earth.	N/A
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	N/A
Power frequency magnetic field (50Hz and 60Hz) IEC 61000-4-8	30A/m.	30A/m.
Power input line voltage dips, short interruptions, and voltage variations IEC 61000-4-11	0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT, 1 cycle and 70%UT, 25/30 cycles Single phase: at 0° 0% UT, 250/300 cycles	N/A

Table 3

Manufacturer's Declaration – Electromagnetic Immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields.

The product is intended for use in the electromagnetic environment specified below. The customers or users should ensure that it is used in such an environment.

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation* 2,1 kHz	65^
13,56 MHz	Pulse modulation* 50 kHz	7,5^

Remarks:
This test is applicable only to the Medical Electrical Equipment or System intended for use in the Home Healthcare Environment
* The carrier shall be modulated using a 50 % duty cycle square wave signal.
^ r.m.s. before modulation is applied.

Table 4

Manufacturer's Declaration – Electromagnetic Immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.

The ELETRA Smart is intended for use in the electromagnetic environment specified below. The user of the ELETRA Smart should assure that it is used in such an environment.

Test Frequency (MHz)	Band* (MHz)	Service*	Modulation^	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380–390	TETRA 400	Pulse Modulation^ 18 Hz	1.8	0.3	27	27
450	430–470	GMRS 460, FRS 460	FM# ± 5 kHz Deviation 1 kHz sine	2	0.3	28	28
710 745 780	704–787	LTE Band 13,17 Hz	Pulse Modulation^ 217 Hz	0.2	0.3	9	9
810 870 930	800–960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse Modulation^ 18 Hz	2	0.3	28	28
1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation^ 217 Hz	2	0.3	28	28

Table 4 (Cont.)

Test Frequency (MHz)	Band* (MHz)	Service*	Modulation^	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation^ 217 Hz	2	0.3	28	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation^ 217 Hz	0.2	0.3	9	9

NOTE: If necessary to achieve the IMMUNITY TE ST LEVEL, the distance between the transmitting antenna and the Medical Electrical Equipment or System may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

Remarks:

* For some services, only the uplink frequencies are included.

^ The carrier shall be modulated using a 50 % duty cycle square wave signal.

As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

ELETRA

Manufacturer Information

Manufacture: Ziyang Freqty Medical Equipment Co., Ltd.
Address: Floor 2-3, Unit 7, Building 3, No. 222, West Section 3, Outer Ring Road, Yanjiang District, Ziyang City, 641300, Sichuan Province, P.R. China
Tel: +86-028-26577388
Email: sales@freqty.com
Website: http://www.freqty.com/

EC REP

European Authorized Representative

Company: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
Contact: Yan Zhang (Ms.)
Tel / Fax: +31(0)10 3034500; +31(0)20 2111106
E-mail: ec.rep@sungogroup.com; yan.zhang@sungoglobal.com

202312