1. TITLE

NivolisAnton Instructions For Use

Remote Monitoring Device for Transcutaneous CO_2 Monitors

2. MANUFACTURER

VIVARDIS SAS, 7 Boulevard Louis Lumière 42000 Saint Etienne, France
TEL : +33 428 04 44 00 - FAX: +33 428 48 00 79 - Web : www.vivardis.fr

3. PUBLICATION OF IFU

4. AUDIT TRAIL

Version	Description	Modification date
01	Initial Version	2022/08/25
02	Updated version	2022/10/21
03	Updated version : figures	2022/12/05
04	Various minor typo updates	2023/01/10
05	Various minor updates	2023/02/16
06	Updated version: label	2023/03/24
07	Update: technical specifications and conformity	2023/04/20
08	Update: Adding Radiometer TCM5 + Corrections + Layout	2024/05/01

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5. TABLE OF CONTENT

6. Introduction & Purpose

Congratulations for choosing **NivolisAnton** remote communication device.
NivolisAnton enables wireless and remote communication from $tcPCO_2$ monitors.
NivolisAnton connects to the serial port, and when relevant to the network port, of the $tcPCO_2$ monitor.
NivolisAnton detects if the monitor is actively measuring blood gas values, collects and transmits the spot check measurements performed by the monitor. At the end of the recording, **NivolisAnton** collects in its internal memory then transmits the recording file from the monitor for transmission to Nivolis' cloud via the **Nivolis-Box** router.
NivolisAnton adheres to the monitor manufacturer's communication protocol.

The aim of this document is to describe and detail the instructions for use of **NivolisAnton** for medical professionals or homecare providers.

7. Intended Use, Indications/Contre-indications

7.1. Intended Use

The intended purpose of NivolisAnton is to collect, store and transmit physiological values collected from an external third party transcutaneous blood gas monitor.
For information : As per the intended use of the third party transcutaneous blood gas monitor, given monitor is intended only as an adjunct in patient assessment by measuring transcutaneously blood gas values such as $tcPCO_2$, $tcPO_2$, SpO_2 and Heart Rate and communicating these values to a digital communication port.
NivolisAnton collects the data provided by the transcutaneous monitor ($tcPCO_2$, $tcPO_2$, SpO_2, Pulse, Perfusion Index and Heating Power) and transmits the collected data to a third party server or another medical device via wireless communication.
NivolisAnton is intended for use at home, long term care or in hospital environment, with the exception of acute care units.
Data transmitted by **NivolisAnton** are the measurements and calculations done by the external transcutaneous blood gas monitor as per to its manufacturer recommendations.
Data transmitted from the monitor through **NivolisAnton** for patient assessment must be used by qualified health practitioners in conjunction with clinical signs and symptoms according to the intended use of the external transcutaneous monitor.

7.2. Intended Indications

NivolisAnton is intended for the patient population, for which the physicians deem necessary to perform a transcutaneous blood gas monitoring.
As per the transcutaneous monitor's intended population, $tcPCO_2$ and $tcPO_2$ monitoring is indicated in adult/pediatric (older than term birth plus 12 months) and neonatal (younger than term birth plus 12 months) patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.

7.3. Contraindications

There are no contraindications to use **NivolisAnton**.

8. LABEL OVERVIEW

8.1. NIVOLISANTON LABEL

8.2. MEANING OF LABEL SYMBOLS

REF	Manufacturer 's model number so that the device may be identified		Device manufacturer
SN	Serial number of the device		Refers the user to consult the Instructions For Use
UDI	Number for Unique Device Identification: (01: Model, 11 : Manufacture Date, 21 : Serial Number)		Data Matrix referring to UDI
www.nivolis.info	URL for the NivolisAnton Instructions For Use	+40°C +10°C	Operating and storage temperatures shall be between+10 and +40 °C
1060hPa 700hPa	Operating & storage atmospheric pressure shall be between 700 & 1060 hPa	95% 10%	Operating and storage relative humidity shall be between 10% and 95%
IP21	Protected from touch by fingers, objects larger than 12 millimeters & against vertically falling water drops		**NivolisAnton** shall be used inside
	Relevant to EU rules on Waste from Electrical and Electronic Equipment (WEEE) & shall be recycled		Use of an induction charger, certified by QI Consortium (compliant to IEC 62368-1:2018
Li-ion	Contains a Li-ion battery which shall be recycled	WiFi	Uses wireless communication modes

9. TRAINING REQUIREMENTS

Read the entire Instructions For Use (IFU) before using your **NivolisAnton** Medical Device.
NivolisAnton's IFU do not replace the Instructions to use of the transcutaneous CO2 Monitor.
The Installation of **NivolisAnton** is detailed in Use's Indications chapter. Manipulation and installation of **NivolisAnton** may be done by health practitioners in a medical environment or by homecare technicians in an home environment. Apart from the Instructions For Use, Healthcare professional do not need a specific training to use **NivolisAnton**.
Consult VIVARDIS, the manufacturer, for any questions regarding **NivolisAnton** (Tel +33 428 04 44 00 | FAX +33 428 48 00 79 | www.vivardis.fr | Ticketing Tool for assistance: https://ticket.vivardis.pro/)

10. WARNINGS, PRECAUTIONS & CONTRAINDICATION FOR USE

Warning **Caution**

	NivolisAnton is **NOT** certified to be used for continuous monitoring where failure to operate can cause injuries or death of the patient.
	When **NivolisAnton** is being charged the ambient temperature shall not exceed 30°C. **NivolisAnton** shall be used with a charger compliant to IEC62368-1:2014+A11:2017. The battery life expectancy of **NivolisAnton** is 500 cycles ~ 80% capacity.
NivolisAnton complies with the international standard IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. That standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of source might disrupt the performance of the device, affecting recorded signals and therefore data analysis and resulting in possible incorrect treatment. Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC), and needs to be installed and put into service according to the EMC information detailed in the section "Electromagnetic Compatibility (EMC) Information" of this manual.	
	Do not use damaged equipment or accessories. This may result in bad performance of **NivolisAnton** or patient/operator injury. There are no user serviceable parts inside **NivolisAnton** . The device should be serviced by authorized parties only. Service performed by non-authorized parties may affect data analysis and result in possible incorrect treatment. The warranty is avoid if **NivolisAnton** is opened.
	No modification of **NivolisAnton** or its accessories is allowed. Un-authorized modifications could result in the device not performing as intended and cause serious harm to the patient. To ensure patient safety and effective use of **NivolisAnton** , only use accessories that have been validated for use by **Vivardis**
	NivolisAnton and its accessories are not designed to secure a specified degree of protection against harmful ingress of liquids. Do not autoclave or immerse the device in any kind of liquids. Ingress of liquids may result in electric shock.
	NivolisAnton and its accessories should always be transported in its accompanying carrying case to ensure adequate protection and prevent damage To prevent cross-contamination, make sure **NivolisAnton** and its accessories are properly cleaned. Please refer to the instructions in "Cleaning Indications" section
	Personal Data Protection: In order to respect Patient Data protection, Vivardis recommends to avoid record patient identifiers, and when applicable, to erase the **Name** and **First Name** fields in the transcutaneous monitor Patient Screen

11. Device Description & applications

NivolisAnton enables wireless and remote communication from $tcPCO_2$ monitors. These monitors are Class IIb Medical Devices which measure transcutaneously CO_2 and O_2 partial pressures in the blood ($tcPCO_2$ & $tcPO_2$) as well as the oxygen saturation of blood haemoglobin (SpO_2).
Some models of these monitors require a drift correction of the $tcPCO_2$ values for long term recording as per the recommendations of the respective manufacturers.
NivolisAnton device connects to the serial and/or network port of the $tcPCO_2$ monitor. NivolisAnton detects if the monitor is actively measuring blood gas values, collects these measurements performed by the monitor by following manufacturer's communication protocol and stores the collected values in its internal memory.
When required and periodically, **NivolisAnton** transmits the crypted collected data to external receiving devices, such as Medical Devices (which are granted approved data access by Vivardis) via Bluetooth or data servers (**NivolisBox** as an example) via WIFI. This data is thereafter transmitted by previously mentioned devices to the **NivolisPortal** server for archiving.
NivolisAnton operates as a stand-alone device connected to the **NivolisBox**.

For information
NivolisBox is a ready-to-use hardware platform serving as a 4G Router and/or as a local web server with a WiFi hotspot access to direct **NivolisAnton**'s data to a remote server when required.
NivolisPortal is a web portal hosted on a local or remote server accessible only to authorized care professionals. The access portal receives the data from NivolisAnton, temporarily archives them and displays them for the care professional

12. Sterilization/No Sterilization

NivolisAnton is a device that is neither sterile nor to be sterilized.

13. Single Use / Single Patient

NivolisAnton is not a single use device.

14. Intended Users & Environments

NivolisAnton is intended to be used in hospital, in long term care site as well as patients' home.
NivolisAnton is not intended to be used in Acute or Intensive Care Units
NivolisAnton users are Healthcare professionals (Physicians, Nurses) or professionals from Homecare providers

15. Expected benefits & Risks

The benefits of NivolisAnton use are :

- remote monitoring of transcutaneous CO2 recordings from third party monitors
- easy use in medical or home environments
- generic use with communication ports on the third party monitors

There is no risk to use NivolisAnton in a medical nor home environment.

16. Clinical Performances

Even if there is no equivalent device of **NivolisAnton**, literature analysis reports great interests for transcutaneous CO_2 monitoring as well as for monitoring devices (telemonitoring or monitoring) for patients with respiratory diseases and respiratory support treatments.
There are no patient side effects to use **NivolisAnton** for remote monitoring.

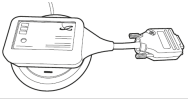
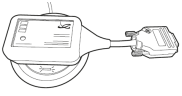
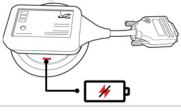
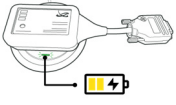
17. Residual Risk, Contraindications & Undesirable Side Effects

According to the performed Risks Analysis, **NivolisAnton** benefits outweigh residual risks.
There is neither contraindications to the use of **NivolisAnton**, nor side effects according to the performed Clinical Evaluation.

18. Indications for use by Care Professionals

18.1. Charging

Before using **NivolisAnton**, you must charge **NivolisAnton**. For this you shall use the induction charger with NivolisAnton in the positions as describes below :
First of all, plug the charger into a power outlet

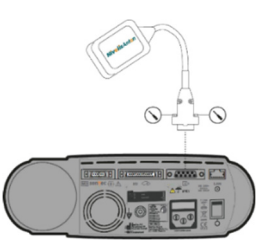
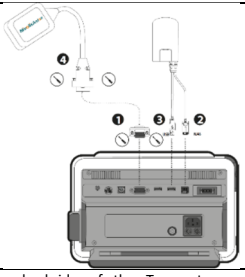
On the lower side of NivolisAnton there is a label indicating the location of the loading area	
Position the label on the induction charger	
Charging Indications	
	
NivolisAnton has an empty battery or is not positioned correctly: the **Red** LED is lighting	NivolisAnton's battery is charging : the charger **Green** LED is blinking

Charging and Operating Indications on NivolisAnton
How to know if NivolisAnton is fully charged ?
When NivolisAnton is charging a **blue** LED is lighting in the opposite side of the connection side.

- When NivolisAnton battery is fully charged : **Green** LED lights up
- When NivolisAnton battery is half charged : **Green** LED flashes 3 times
- When NivolisAnton Battery is discharged : **Green** LED flashes 5 times

How to know if NivolisAnton is Operating ?
When the **Green** LED flashes every 10 seconds it means that **NivolisAnton** is Operating.
When the **Green** LED does not light up or does not blink, it means that **NivolisAnton** is fully discharged and **NivolisAnton** needs to be charged or **NivolisAnton** is in charge.

18.2. CONNECTION-SETUP OF TRANSCUTANEOUS CO_2 MONITORS

Sentec SDM Monitor	Radiometer TCM5 Monitor
	
On the backside of the Transcutaneous CO_2 Monitor, connect **NivolisAnton** to the Monitor Serial Port as indicated.	On the backside of the Transcutaneous CO_2 Monitor, connect **NivolisAnton** to the Monitor Serial Port as indicated.
Attach/screw the RS232 connector of **NivolisAnton**	Attach the RS232 connector of NivolisAnton Insert the RJ45 and the USB connectors into the corresponding sockets of the TCM5
Software settings	**Software settings**
Menu Interfaces -> Serial Interface	Select Menu > Technical Enter the Technical Menu password.
SentecLink Protocol	**Serial Port**
Baud rate (SentecLink) **115200**	**1.** Select *Connectivity* > *Serial*. **2.** Select the **MonLink** 2.0 protocol **3.** Select *Export Format* (TCM4 ou TCM5) depending on your analysis software **4.** Select *Apply* or *Return* (<)
	Network:
	5. Select Connectivity > Ethernet. **6.** Activate the Network (if inactive). **7.** Deactivate DHCP (if active). **8.** Select *Apply*. **9.** Enter the IP address **192.168.254.102** **10.** Enter the Gateway **192.168.254.254**, SubNet Mask **255.255.255.0**, DNS1 **192.168.254.254** & DNS2 **192.168.0.2** **11.** Select *Apply*.
	⚠ **Personal data protection** ⚠
	To guarantee the best personal data protection, please ensure to erase the fields **Name** & **First Name** (**"Patient Menu"**)
	⚠ **Identitovigilance (CSV - TCM4 format)** ⚠
	Enter TCM5's serial number in the ID Patient field to improve traceability of TCM5 files

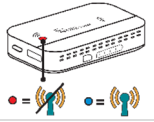
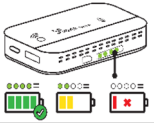
When **NivolisAnton** is operating, the **Green** LED blinks every 30 seconds.

18.3. WIRELESS 4G NETWORK CONNECTION

As described in *Device Description and Applications* section, NivolisAnton operates as an accessory of a transcutaneous CO_2 monitor.

The transmission of data collected by **NivolisAnton** to **NivolisPortal** needs **NivolisBox**. The communication from **NivolisAnton** to **NivolisBox** is already preconfigured.

Ensure that NivolisAnton is fully charged, that NivolisBox is operating

Indications for NivolisBox	
Click **ONCE** the button to start **NivolisBox** Click **TWICE** the button to stop **NivolisBox**	
Red Light : Not connected to 4G network **Blue** Light : Connected to 4G network Blinking **Blue** Light : Communicating via 4G	
Charge level	

18.4. NIVOLISANTON DATA ACCESS: REMOTE CONNECTION

How to connect to collected NivolisAnton data?

- Open your Internet Browser (Chrome, Edge, Firefox, Safari...)
- Enter the site in the address bar : https://nivolis.pro/ or https://prisma.nivolis.pro/
- Access is possible only to registered users
- The user has to accept to use his email and phone to secure the access to the website

Refer to the user instructions of NivolisPortal (nivolis.pro) for the use of the website and the extraction of NivolisAnton's collected data.

19. TRANSPORT, STORAGE & HANDLING INDICATIONS

19.1. TRANSPORT

NivolisAnton is delivered :

- in a specific pouch with this manual
- with an induction charger
- with a **NivolisBox** for wireless transmission of data
- When applicable for the Radiometer TCM5 with a RS232 adapter and a network adapter.

NivolisAnton' setup shall be done after training of the care providers (Hospital Use and Home Use).

19.2. STORAGE

When **NivolisAnton** is not used, each **NivolisAnton** shall be :

- cleaned according to the instructions for cleaning
- stored in its own pouch

19.3. HANDLING

There are no particular recommendations to handle **NivolisAnton**, except to avoid dropping the device on the ground: a fall-height greater than 1 meter could be a risk damaging the device. Please contact the manufacturer in case of a broken device

20. CLEANING INDICATIONS

This section details cleaning indications of **NivolisAnton**.
Who may clean **NivolisAnton** ?

- Medical Environment: Healthcare Professional
- Home Environment: Homecare Provider

When shall **NivolisAnton** be cleaned?

- you used **NivolisAnton** for a patient and you want to store **NivolisAnton**
- you used **NivolisAnton** for a patient and you need use it for another patient
- **NivolisAnton** is dirty

How to proceed for cleaning **NivolisAnton** ?

- Clean the enclosure surface with a disinfectant/detergent such as Wip'Anios Excel wipes
- Wait 5 minutes before handling the device

21. INFORMATIONS NÉCESSAIRES À UNE INSTALLATION CORRECTE

Before using **NivolisAnton**, charge it with the induction charger and read the Instructions For Use.
When **NivolisAnton** is charging a **Blue** LED lights up.
When the **Green** Led flashes every 10 secondes it means that **NivolisAnton** is operating.
When the **Green** Led does not light up or does not flashes it means that **NivolisAnton** is fully discharged and **NivolisAnton** needs to be charged.

22. USE WITH EXTERNAL DEVICES

NivolisAnton shall be connected to the serial port of transcutaneous CO_2 monitors.
Transcutaneous CO_2 monitors are defined by their respective manufacturers as devices not intended for diagnosis, but intended only as an adjunct in patient assessment. They must be used in conjunction with clinical signs and symptoms.
Likewise, **NivolisAnton** is a device collecting and transferring unaltered data from these monitors and does not measure transcutaneous parameters directly from the patient.

23. WARNING & PRECAUTIONS FOR DEVICE DISPOSAL

NivolisAnton is an electronic equipment and is concerned by EU rules on Waste from Electrical and Electronic Equipment (WEEE) and shall be recycled. The warnings are on **NivolisAnton's** label :

NivolisAnton is concerned by EU rules on Waste from Electrical and Electronic Equipment (WEEE) and shall be recycled

NivolisAnton contains a Li-ion battery which shall be recycled

24. TROUBLESHOOTING

If you encounter any problems, have a look at the following troubleshooting topics

Problem/possible cause	Solution
Led of the induction charger doesn't light up	Check that the induction charger is plugged into an electrical outlet

When NivolisAnton is placed upon the induction charger, the LED of the charger doesn't light up	Check that NivolisAnton is on the right side : the indicator on the charger side
When NivolisAnton is placed upon the induction charger, NivolisAnton blue LED does not light up	Check that NivolisAnton is on the right side : the indicator on the charger side Check that the charger is connected to an electrical outlet
Impossible to attach NivolisAnton to monitor's serial port	Check that you are on the correct monitor's port
The wireless connection with **NivolisAnton** is not possible	Check that **NivolisBox** works (plugged into an electrical outlet or charged)
No data collected or incomplete recording	Check that NivolisAnton is correctly connected Check that capnia monitor works correctly, please read the capnia monitor's IFU

25. INCIDENT

Any serious incident shall be notified to NivolisAnton's manufacturer (ie VIVARDIS) as well as the Competent Authority of the member state in which the user or the patients.
Vivardis 7 Boulevard Louis Lumière 42000 Saint Etienne, France
Téléphone : +33 428 04 44 00; Télécopie : +33 428 48 00 79; Web : www.vivardis.fr

26. SOFTWARE - NETWORK

Minimal Software Requirements (Web browser for local or server access to **NivolisAnton** data)

Chrome	Edge	Firefox	Internet Explorer	Opera	Safari	Chrome Android	Firefox for Android	Opera Android	Safari on iOS	Samsung Internet	WebView Android	Deno
✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗

Network used:

- **NivolisAnton** transmits data to NivolisBox via a crypted WIFI network

Cybersecurity measures:

- **NivolisAnton** data security is ensured by a double 256 bytes encryption
- **NivolisAnton** data integrity is performed by a 256 bytes hashing
- Server access to **NivolisAnton** data is performed using a two factors authentication: identification + password and a SMS code
- No remote access via wireless means is possible on **NivolisAnton's** microcontroller
- Provided the recommendations of § 18.2. Connection-Setup of transcutaneous CO2 monitors on page 9 are met, data collected by NivolisAnton are not considered to be personal data and are not subject to GDPR.

27. SPECIFICATIONS - DECLARATION OF CONFORMITY

27.1. DECLARATION OF CONFORMITY

NivolisAnton complies with

- IEC 60601-1:2005 & /AMD1:2012 & /AMD2:2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment: General requirements for basic safety & essential performance, Collateral Standard: Electromagnetic disturbances, Requirements & tests
- IEC 60601-1-11:2015 & /AMD1:2020: Medical electrical equipment: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 301489-1 & -17 V2.2.3: Electromagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: & 17
- EN 300328 V2.2.2: Wideband transmission systems - Data transmission equipment operating in the 2,4 GHz band - Harmonized Standard for access to radio spectrum

27.2. TECHNICAL SPECIFICATIONS

27.2.1. Physical Dimensions:

Dimensions	Body : 7 cm (L) x 4,8 cm (W) x 2,7 cm (H) - Cable: 18.5 cm	**Weight** 130 g

27.2.2. Environmental Conditions:

Temperature: NivolisAnton operating and storage temperatures shall be between +10°C & +40°C Ambient temperature during charging shall not exceed 30°C - NivolisAnton temperature will not exceed 40°C as measured during a controlled environment test..
Humidity: NivolisAnton operating and storage relative humidity shall be between 10% and 95% **NivolisAnton** shall be used inside. **NivolisAnton** is protected from touch by fingers, objects larger than 12 millimeters and against vertically falling water drops (IP21).
Pressure: NivolisAnton's operating & storage atmospheric pressure shall be between 700 & 1060 hPa

27.2.3. Power Specifications

Battery Type	Internal rechargeable LiPo battery, compliant to IEC62133-2:2017
Battery Specifications	Nominal capacity: > 1900 mAh | Nominal voltage : 3,7 V
Charging Specifications	The wireless charger shall be compliant to EN303417 standard (Qi) with a rated power < 10W

27.2.4. Memory Specifications

Memory	Non Volatile Flash memory with 16 Mbytes capacity

27.2.5. WIFI & Bluetooth Specifications

Conformity	WIFI Version 802.11 BGN	Bluetooth Version 4.2	
Operating frequency	WIFI : 2.412 - 2.472 GHz		BLE : 2.402 - 2.480 GHz
Output power	WIFI :	802.11 b : 19.14 dBm 802.11 n20 : 18.96 dBm, Bluetooth LE : 5.93 dBm	802.11 g : 19.22 dBm, 802.11 n40 : 19.12 dBm
Operating range	WIFI : > 10 meters in ideal conditions, without obstacles		

CERTIFICATION OF ACCESSORIES

CE

Declaration of conformity

We, the manufacturer / importer,
Rapoo Europe B.V.
Weg en Bos 132 C/D,
2661GX Bergschenhoek, Netherlands
Declare that the product
Product name wireless charger
Model No. XC140
Complies with the following norms of:
EN 303 417 V1.1.1(2017-09)
EN 301 489-1 V2.2.1 (2017-02) EN 301 489-3 V2.1.1 (2019-03)
IEC 62368-1:2014+A11:2017
EN 62311:2018
IEC62321-3-1:2013; IEC62321-4:2013+AMD1:2017;
IEC62321-5:2013; IEC62321-7-1:2015; IEC62321-7-2:2017;
IEC62321-6:2015; IEC62321-8:2017 ;

EN 55032:2015
EN 55035:2017
EN 61000-3-2:2014
EN 61000-3-3:2013
EN62368-1:2014+A11:2017
EN 50563-2011/A1:2013

This product is in conformity with the essential requirements of the Radio Equipment Directive 2014/53/EU; and the RoHS Directive 2011/65/EU and its amendment directive 2015/863/EU. The lab Shenzhen Anbotek Compliance Laboratory performed a conformity assessment according to Annex III, Module B.

B.Blankert
Director
Bergschenhoek; 10-12-2019

qi FC CE RoHS

BST A RELIABLE TESTING FOR TRUST

EC-RED Certificate

No.: BSTXD230322434601EC

Submitter : SHENZHEN SHUOTIAN INFORMATION TECHNOLOGY CO., LTD
5F,Shenzhou Computer Building,Madame Curie Avenue,Bantian Street,Longgang District,Shenzhen,Guangdong Province,China

Manufacturer : SHENZHEN SHUOTIAN INFORMATION TECHNOLOGY CO., LTD
5F,Shenzhou Computer Building,Madame Curie Avenue,Bantian Street,Longgang District,Shenzhen,Guangdong Province,China

Product : 4Gmifi
Trade name : Sailsky

M/N : XM42,XM-W180,XM-W210,XM-W300,XM-W310,XM-W380,XM-M300, XV-M305,XM-M308,XM-M312,XM-M320,XM-M500,XM-M905,XM40, XM41,XM42,XM206,XM207,XM208,XM280,XM210,XM286,XM220, XM220B,XM220C,XM301,XM310,XM311,XM312,XM322,XM325, XM315,XM239,XM900

Essential requirement		Applied Specifications, Standards	Documentary Evidence	Result
Art.3.1(a)	Safety	EN IEC 62368-1:2020+A11:2020	BSTXD230322434601SR	Pass
Art.3.1(b)	EMC	ETSI EN 301 489-1 V2.2.3 (2019-11) ETSI EN 301 489-17 V3.2.4 (2020-09)	BSTXD230322434601ER	Pass
Art.3.2	Radio	EN 300 328 V2.2.2 (2019-07)	BSTXD230322434601RF	Pass
Art.3.1(a)	Health	EN 62479:2010	BSTXD230322434601EM	Pass

The EUT described above has been tested by us with the listed standards and found in compliance with the council RED directive 2014/53/EU. It is possible to use CE marking to demonstrate the compliance with this Directive.
The scope of evaluation relates to the submitted documents only.

CE

Christina Ding
Manager
Mar. 20, 2023

BST Technology (Shenzhen) Co.,Ltd.
Add: No.7, New Era Industrial Zone, Guanlan, Baoan District, Shenzhen, Guangdong, China
Certificate Search: http://www.bst-lab.com Tel:400-882-9628, 00000000305, E-mail:christina@bst-lab.com

ATC

CERTIFICATE

of Conformity
EC Council Directive 2014/53/EU
Radio Equipment

Registration No.: ATE20171748, ATE20171749, ATE20171750, ATS2017554

Applicant: Shenzhen HouTian Network Communication Technology Co., Ltd
Floor 3, Building B, No.29 Longfeng Road, Long Gang District, Shenzhen City, Guangdong Province, China.

Product: WiFi bridge&repeater

Identification: Model No. : VAP11N-300
Trade Mark : VONETS
Test Voltage : DC 5V(Powered by Adapter)

Standards: Draft EN 301 489-1 V2.2.0: 2017 EN 301 489-17 V3.1.1: 2017
EN 300 328 V2.1.1: 2016 EN 62311: 2008
EN 62368-1: 2014

The certificate of conformity is base on an evaluation of a sample of the above-mentioned product. Technical report and documentation are at the applicant's disposal. This is to certify that the tested sample is in conformity with all provisions of Article 3 of Council Directive 2014/53/EU, referred to as the Radio Equipment Directive. This certificate does not imply assessment of the production and does not permit the use of ATC's logo. The applicant of the certificate is authorized to use this certificate in connection with the EU declaration of conformity according to Annex VI of the Directive.

Aug. 31, 2017
Date

Certified by
Sean Liu

CE The CE Marking may only be used if all relevant and effective EC Directives are complied with. CE

Shenzhen Accurate Technology Co., Ltd - 1/F., Building A, Changyuan New Material Port, Science & Industry Park, Nanshan District, Shenzhen, Guangdong, P.R. China.
Tel.: +86-755-2650 3290 Fax: +86-755-2650 3396 E-mail: webmaster@atc-lab.com

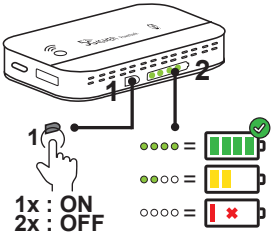
NOTES

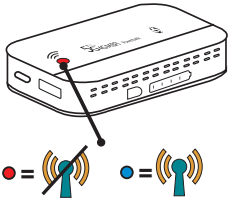
Certification of the device supported by La Région Auvergne-Rhône-Alpes

NivolisAnton

Vivardis

1.





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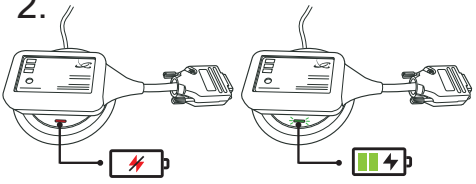

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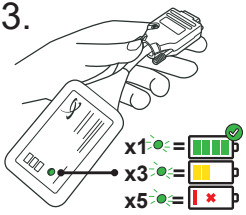

4.