

## **GENERAL CONDITIONS OF USE OF THE BORA CARE SOLUTION**

These General Conditions of Use (GCU) apply in their entirety to all use of the BORA CARE Solution, published by BIOSENCY, a simplified joint stock company with capital of €507,130, whose registered office is located at 8 bis rue du Pressoir Godier, 35760 Saint-Grégoire, France, registered in the Trade and Companies Register under number 830 861 860 00013 RCS Rennes (hereinafter referred to as "BIOSENCY").

**Therefore, any use of the BORA CARE Solution implies unreserved acceptance of these General Conditions.**

The GCU come into force for the User on the day of their acceptance from the User Account opening page, which is personal to the User.

### **I - DEFINITIONS**

Whenever they are used in the body of these General Conditions, the terms below shall have the following definition:

***Accessories:***

The accessories for the BORA BAND bracelet comply with current standards and enable it to be attached and powered.

***Administrator(s):***

Any natural person(s) authorised by the CUSTOMER to create and manage Patient Accounts and Employee Accounts on the latter's behalf.

***Distributor Administrator(s):***

Any natural person(s) authorised by the Distributor to create and manage Administrator Accounts for Customers on behalf of the Distributor.

***General Administrator:***

A BIOSENCY account manager who intervenes for second-level maintenance in the event of a malfunction of the Platform encountered by one of the Users and after the unsuccessful intervention of the Administrator or the Distributor Administrator where applicable.

***"BORA BAND" bracelet(s):***

A portable medical device designed by BIOSENCY to measure physiological parameters for chronic respiratory insufficiency.

***Employee(s):***

Any natural person(s) in charge of the remote monitoring of Patients on behalf of the Customer.

***CUSTOMER:***

Any legal entity(ies) or professional(s) authorised by the competent health authority to ensure the remote monitoring of Patients in accordance with the purpose of the BORA CARE Solution, such as home health care providers (PSAD), health establishments (hospitals, clinics, dispensaries), nursing homes, self-employed health professionals, or any other health or medico-social structure, having purchased a Subscription directly from BIOSENCY or from a BIOSENCY distributor with a view to making the BORA CARE Solution available to Patients.

***Distributor:***

Any legal entity having concluded a distribution contract for the BORA CARE solution with BIOSENCY.

***Patient(s):***

Any patient(s) of the CUSTOMER to whom the CUSTOMER provides the BORA CARE Solution for a specific period of time.

***Platform / "BORA CONNECT" platform:***

Medical device corresponding to a web platform in SaaS mode accessible at the following address <https://bora-connect.com> from a computer or mobile application by Users with an Account.

**Healthcare professional(s):**

Any healthcare professional who participates in the care of a Patient and who is authorised to consult, via a Healthcare Professional Account, the data generated as part of the remote monitoring provided by the CUSTOMER.

**Solution / "BORA CARE" solution:**

The remote monitoring and prevention solution dedicated to chronic respiratory insufficiency and published by BIOSENCY, described in the Subscription Contract and including in particular: access and rights of use relating to the BORA CONNECT Platform, described in the instructions for use, or a Hardware Kit consisting of the Hardware and Accessories made available, or both.

**User(s):**

All Patient(s), Employee(s), Healthcare Professional(s), Administrator(s) excluding Distributor Administrator(s).

**II - PURPOSE**

These GCU are intended to govern the use of the BORA CARE Solution by the User. Their purpose is to define the rules of use of the BORA CARE Solution as well as the respective rights and obligations of Users, Distributor Administrators and BIOSENCY.

**III - CONDITIONS OF ACCESS AND USE**

**1. Purpose of the BORA CARE Solution – Conformity of use to its purpose**

The use of the BORA CARE Solution by any User is subject to these GCU and to the laws and regulations in force.

All Users will be informed, on <https://doc.bora-connect.com> of the essential characteristics, contraindications and limitations of the BORA CARE Solution, in particular the instructions for use for the BORA CONNECT Platform and the BORA BAND Bracelet.

The BORA CARE Solution must be used in accordance with the instructions for use provided by BIOSENCY to Distributor or to the CUSTOMER. It is intended to:

- record physiological parameters, in particular cardiorespiratory parameters, periodically using compatible medical devices described in the instructions for use.
- display this data on a web platform for remote monitoring by a Healthcare Professional. This information can be used to monitor the physiological state of patients, using visual notifications.

**The BORA CARE solution is not suitable for continuous monitoring of the patient's physiological parameters, and no alarms are provided.**

**2. Access to the Platform – User Accounts**

The BORA CARE Solution is made available to Users via the website at the following address <https://bora-connect.com> and a mobile application by means of an identifier and an access code.

Any use of the BORA CARE Solution implies the prior activation of an Account. Each Account is personal and non-transferable.

The User acknowledges that he/she is accessing a Platform or a mobile application with secure access methods. They undertake not to disclose their authentication details to third parties.

Connection to the personal User Account is based on a reliable and secure User authentication system. Any action carried out by the User via their Personal Account, using their authentication details, will be deemed to have been carried out by the User and under their sole responsibility.

Separate Accounts will be allocated according to the User's profile:

- the Employee Account enables remote monitoring of Patients; the identifier and access code will be allocated by the Administrator;
- the Patient Account enables Patients to access their data history; the identifier and access code will be allocated by the Administrator or the Healthcare Professional;
- the Healthcare Professional Account enables remote monitoring of Patients; the identifier and access code can be allocated by BIOSENCY.
- The Administrator Account is used to manage Patient Accounts, Employee Accounts and Administrator Accounts; the identifier and access code can be assigned by BIOSENCY or by an Administrator.

When creating their personal Account, Users undertake to enter the data enabling them to be identified under their sole responsibility, control and direction and undertake to provide complete, accurate and up-to-date information, and not to usurp the identity of a third party, nor to hide or change their age.

In the event that the User communicates false, inaccurate, misleading, incomplete or outdated information, BIOSENCY reserves the right to suspend or refuse access to the Platform.

Users may only use the Platform within the framework and for the purpose permitted by the User Account allocated to them.

Any non-conforming use will lead BIOSENCY to suspend access to the Solution.

In the event of loss or theft of authentication details, or suspicion of their use by an unauthorised third party, the User undertakes to inform Biosency without delay.

The request for invalidation notified by the User in the event of loss or theft or suspected use by an unauthorised third party of his/her authentication details will take effect immediately from the date of such notification.

The User's authentication elements will be deactivated by BIOSENCY as soon as possible and new provisional authentication elements will be sent to the User.

The User must change his/her password the next time he/she logs on.

### **3. Technical requirements, configurations and updates**

To be able to use the BORA CARE Solution, all Users must have an Internet access subscription and ensure that the configuration of their computer hardware is suitable and compatible.

The User acknowledges and accepts that the entire cost of connecting to the Internet is borne exclusively by the User.

The User must also have a mobile phone number to receive the User Account access code by SMS, failing which they will not be able to use the BORA CARE Solution.

To use the Platform, you need to have the following requirements: a sufficiently fast internet connection and a computer and/or smartphone.

BIOSENCY reserves the right to make changes to the BORA CARE Solution. Technical modifications may be made without prior notice.

The User must use the current validated version of the BORA CARE Solution. Under no circumstances may an older version of the Solution be used. The User may not use any technical means to prevent the updating of the Solution.

The Solution and its services are accessible 24 hours a day, 7 days a week, subject to suspension due to breakdowns, failures or paralysis of the network, the system and/or the means of communication, as well as maintenance and correction work required to update and ensure the proper operation of the Solution.

#### **4. Prior to accessing the User Account - Acceptance of the GCU and acknowledgement of the Personal Data Protection Policy**

Access to the Solution is only granted after a procedure has been followed to ensure that the User accepts the GCU, agrees to the processing of patient health data and has read the Personal Data Protection Policy concerning the collection of their data, which can be accessed by the User at the following address: <https://doc.bora-connect.com>.

#### **5. Electronic identification with Pro Santé Connect**

Pro Santé Connect is a teleservice set up by the Agence du Numérique en Santé (ANS) to help simplify the electronic identification of healthcare professionals.

Users can connect using their CPS card, with a card reader and the necessary components. The general conditions of use for Pro Santé Connect are available on the ANS website.

### **IV - RIGHTS OF USE**

#### **1. Intellectual property**

The BORA CARE Solution, including the BORA BAND Bracelets and the BORA CONNECT Platform, as well as the Accessories and Hardware and Services, are protected by BIOSENCY's intellectual property rights.

The General Conditions of Use have neither the purpose nor the effect of conferring intellectual property rights of BIOSENCY, of any nature whatsoever (in particular patents, trademarks, copyrights, designs and models, in particular relating to patentable or unpatentable inventions, knowledge, know-how, logos, etc.), to the User or the Administrator.

The User and/or the Administrator is not authorized to file patent applications or claim other intellectual property rights on the basis of the information communicated by BIOSENCY in execution of the General Conditions of Use.

The User and/or the Administrator is not authorised to use the intellectual property rights of BIOSENCY other than as expressly provided for in the General Conditions of Use. The User shall refrain from any action likely to infringe this property right.

#### **2. Duration of use**

The duration of use of the BORA CARE Solution is limited to the duration of opening and validity of the corresponding User Account. This duration cannot exceed the duration of the CUSTOMER's Subscription Contract to the BORA CARE Solution. All User Accounts will be closed and rights of use terminated at the end of the Subscription Contract signed by the CUSTOMER.

User Accounts may also be closed and rights of use terminated in the event of a breach of any of the obligations described in these GCU or in current legislation.

Users may close their User Account at any time. Employee and Patient Accounts may be closed at the User's request to the Administrator. Administrator Accounts and Healthcare Professional Accounts may be closed at the User's request to the Administrator.

Administrator Accounts may be closed at the request of the Administrator Account manager to BIOSENCY. Closing a Personal Account does not automatically delete all personal data concerning the User, which will be retained under the conditions described in the Personal Data Protection Policy.

Users will no longer be able to access the Solution once their Account has been closed.

### **3. Scope of the rights of use granted**

The User has a non-exclusive right to use the Solution, for the sole purpose of using their User Account, for the duration of use.

Unless otherwise agreed in writing by BIOSENCY, Users and Administrators shall refrain from any type of use not expressly authorised by the present General Conditions.

In general and unless otherwise agreed in writing by BIOSENCY, Users will use the Solution in accordance with the general conditions of use as published by BIOSENCY.

In particular, Users shall not:

- post, broadcast, download and/or transmit, by e-mail or in any other way, any content:
  - o contrary to public order or public decency, offensive, defamatory, racist, xenophobic, revisionist or damaging to the honour or reputation of others;
  - o inciting hatred or discrimination against a person or group of persons on the grounds of their sex, origin or membership or non-membership of a particular ethnic group, nation, race or religion;
  - o threatening a person or a group of persons;
  - o that would be inappropriate for its intended audience;
  - o of a pornographic, paedophilic or zoophilic nature;
  - o inciting to commit an offence, a violent act, a crime or an act of terrorism or glorifying war crimes or crimes against humanity or inciting to suicide;
  - o in violation of the privacy of correspondence;
  - o that would be misleading or inconsistent with reality;
  - o comprising, but not limited to, computer viruses or any other code, files or programs designed to interrupt, destroy or limit the functionality of any software, computer or telecommunications equipment;
  - o enabling third parties to obtain, directly or indirectly, pirated software, software serial numbers, software enabling acts of piracy and intrusion into computer and telecommunications systems, viruses and, in general, any software or other tool enabling the rights of others and the security of persons and property to be infringed;
  - o which, in general, would be contrary to the law in force in France;
- disrupt the normal flow of dialogue, accelerate the rate at which the screen scrolls so that Users are unable to follow and type their dialogue, or commit any other action that has a similar disruptive effect on Users' ability to communicate in real time;
- hinder or disrupt the services of the Solution, the servers or the networks connected to the Services, or refuse to comply with the required conditions, procedures, general rules or regulatory provisions applicable to the networks connected to the Services;
- use the Solution in a way that could, in any way whatsoever:
  - o prejudice the rights and interests of third parties;
  - o render inoperable, overload or damage the Platform and/or its services;
  - o hinder and prevent the normal use and enjoyment of the Solution by other Users;
- attempt to mislead BIOSENCY by usurping the name or corporate name of other persons;
- forge headers or otherwise manipulate the identifier in such a way as to conceal the origin of the content transmitted via the Platform;
- reproduce, copy, resell or exploit for any commercial purpose whatsoever all or part of the Services, any use of the Services or any right of access to the Services;
- intentionally or unintentionally violate any applicable national or international law or regulation.

Users and Administrators are solely and entirely responsible for the content they display, send, download and/or transmit, by electronic mail or in any other way, on the Solution, and BIOSENCY cannot be held liable in this respect.

Generally speaking, in the event of non-performance by a User or Administrator of any of their obligations under these General Conditions or any other specific contractual stipulation, their corresponding rights of use may be immediately and automatically suspended and/or terminated by simple notice.

## **V – LIABILITIES – WARNINGS**

### **1. User warnings**

The User acknowledges that their use of the information and functionalities of the solution is under their sole control, direction and responsibility.

### **2. Specific warnings for CUSTOMERS and Healthcare Professionals**

As a reminder, the healthcare professional's liability when using telemonitoring is the same as in their other professional activities. They are solely responsible for their professional judgement and accept full professional liability.

The organisation of remote monitoring may provide for the use of cooperation protocols as defined in Article 66 of the OTSS Law of 24 July 2019. Within this framework, healthcare professionals working as a team can, on their own initiative, embark on a cooperative approach to better meet patients' needs. Through cooperation protocols, they transfer activities or acts of care or risk prevention between themselves, or reorganise the way they work with patients.

Employees and Healthcare Professionals will be able to access the data of Patients for whom they are responsible for remote monitoring, after strong authentication, in compliance with professional secrecy and the rules governing the exchange and sharing of data covered by medical secrecy (article L1110-4 of the French Public Health Code and the corresponding criminal penalties) to which they are subject. It is their responsibility to inform and obtain the consent of Patients where this is required.

The attention of Employees and Healthcare Professionals is drawn to the fact that their User Accounts may contain data relating to the health of Patients. Given their sensitivity, users are warned of the need to monitor third party access to their Accounts. Employees and Healthcare Professionals are responsible for implementing all useful and relevant security measures to protect access to their personal User Accounts.

The use of the Solution by Employees and Healthcare Professionals in the context of patient monitoring does not dilute their legal, regulatory and ethical obligations or their professional liability. They use the Solution under their sole control, direction and responsibility.

BIOSENCY cannot be held responsible for the interpretation or use of the data obtained via the Solution, nor for the consequences arising therefrom.

### **3. Liabilities of Biosency**

As a manufacturer, BIOSENCY guarantees the compliance of the BORA BAND Bracelets and the BORA CONNECT Platform, as medical devices, with the applicable French and European regulations and standards.

The BORA CARE Solution has been designed to comply with the regulations applicable in France, including the European regulations applicable in France. If the BORA CARE Solution is made available and used outside French territory, it is the CUSTOMER's responsibility to ensure in advance that local regulations and standards allow this.

**The BORA CARE Solution must be used in accordance with the instructions for use supplied by BIOSENCY, for the purpose stated in the instructions. BIOSENCY may not be held liable in the event of use that does not comply with the instructions for use. In particular, as indicated in the instructions for use, the Bora Solution must not be used for continuous monitoring: the BORA Band bracelet is intended to record physiological parameters (in particular SpO2, respiratory rate, heart rate) periodically and no alarm is provided to enable continuous monitoring. The BORA CARE Solution is not suitable for emergency or intensive care units.**

In particular, BIOSENCY may not be held liable for any damage resulting from:

- ✓ use of all or part of the BORA CARE Solution that does not comply with the instructions for use;
- ✓ a malfunction of all or part of the BORA CARE Solution which:
  - is caused by modifications made to all or part of the components of the BORA CARE Solution, by any third party not authorised by BIOSENCY;
  - is not attributable to the BORA CARE Solution. Also, BIOSENCY shall not be held liable for:
- ✓ damage to property other than the BORA CARE Solution;
- ✓ the suitability of the BORA CARE Solution for the Users' needs (which is a matter for the Users to decide);
- ✓ any contamination of Users' files by a virus and any harmful consequences of such contamination.

**BIOSENCY will not be liable for unforeseeable damages, nor for indirect and/or immaterial damages such as loss of earnings, financial damages, commercial damages, loss of clientele, loss of orders, or damage of an emotional or private nature, consecutive to its interventions and services.**

BIOSENCY may in no way be held liable for acts relating to the activity of the CUSTOMER and the Healthcare Professionals.

BIOSENCY shall not be held liable in the event of force majeure as defined below:

Force Majeure: The following are considered to be cases of force majeure with regard to BIOSENCY's obligations: force majeure events as defined by article 1218 of the French Civil Code and, more broadly, cases of war, epidemics, pandemics, explosions, acts of vandalism, riots, popular uprisings, acts of terrorism, machine breakdown, fire, storms, water damage, total or partial strikes, acts of government, legislative or regulatory provisions, blockages and failures of means of transport or supply of telecommunications networks, blockages and failures of computer networks (including the switched networks of telecommunications operators), failures of the public electricity distribution network, or loss of Internet connectivity, which would be of a nature to delay or prevent the execution of BIOSENCY's commitments.

BIOSENCY reserves the right to temporarily or definitively suspend access to the Solution, without delay or compensation of any kind whatsoever, in the event of force majeure or technical or regulatory events beyond its control.

#### **4. Liability of Distributors**

The Solution can be implemented by an Authorised Distributor.

In this case, any person who has been licensed to use the BORA CARE solution by an Authorized Distributor must direct all enquiries related to pricing, maintenance, operation of the platform or any other problem that may be related to the use of the BORA CARE solution directly to that Distributor. Biosency will not be held responsible for any problems related to the use of the BORA CARE solution by the network of users created by the Distributor.

## **VI – SECURITY – PERSONAL DATA**

### **1. Hosting:**

BIOSENCY has the Platform hosted by Pictime, a company certified as a Health Data Host.

### **2. Reversibility:**

BIOSENCY undertakes to ensure the reversibility of data uploaded to the Platform by the CUSTOMER, Administrators, Employees and Patients in a usable format.

### **3. Personal data**

Users' personal data are processed by BIOSENCY in accordance with the Personal Data Protection Policy accessible at the following address: <https://doc.bora-connect.com/>.

### **VII - AMENDMENTS TO THE GCU AND ASSIGNMENT**

BIOSENCY reserves the right to modify the present GCU or the rules concerning the use of the BORA CARE Solution at any time.

Any other condition in contradiction with the present General Conditions will only be applicable if it has been expressly accepted in writing by BIOSENCY.

Users will be notified of any changes made via the BORA CARE Solution or by email. The User may then be asked to accept them again. Continued use of the Solution after any change to the GCU implies acceptance of the changes to the GCU.

BIOSENCY may assign these GCU at any time to a subsidiary or successor, regardless of the transaction. The User is not authorised to assign the rights it holds in application of the present GCU to a third party, without the express and prior authorisation of BIOSENCY.

### **VIII - APPLICABLE LAW – JURISDICTION**

These General Conditions are governed by French law. In the event of a dispute, unless otherwise provided by applicable public policy, any dispute relating to the present General Conditions WILL BE UNDER THE EXCLUSIVE JURISDICTION OF THE COMMERCIAL COURT (FRANCE) IN THE REGION OF BIOSENCY'S HEAD OFFICE, EVEN IN THE EVENT OF A SUMMARY PROCEDURE, INTRODUCTION OF THIRD PARTIES, AN INTERLOCUTORY APPLICATION OR PLURALITY OF DEFENDANTS.