QUALITY ASSURANCE CONTRACT FOR THE BORA CARE SOLUTION

Between :
The company BiOSENCY, a simplified joint stock company with a capital of € 464,850, whose registered office is located at 8 bis rue du Pressoir Godier, 35760 Saint-Grégoire, registered in the Trade and Companies Register under number 830 861 860 00013 RCS Rennes, represented by its President, Marie Pirotais (hereinafter "**BiOSENCY**"), of the one part,

And the "**CLIENT**", on the other hand,

Being also, individually or collectively, referred to as the Party or Parties.

Definitions

Label	Written, printed or graphic information either on the device itself, on the packaging of each unit or on the packaging of multiple devices (Article 2.13 of the Regulation)
Serious incident	Any incident that directly or indirectly resulted, may have resulted or may result in - the death of a patient, user or any other person ; - a serious temporary or permanent deterioration in the state of health of a patient, user or any other person - a serious threat to public health (Article 2.65 of the Regulation)
Material	All medical device(s) and hardware (and their accessories) associated with the BORA CARE Solution, described in the Subscription Agreement.
Serious threat to public health	An event that may result in an imminent risk of death, serious deterioration of health or serious illness that may require prompt remedial action, and that may result in significant morbidity or mortality in humans or that is unusual or unexpected at the time and place concerned. (Article 2.66 of the Regulation)
Corrective action	Any action to eliminate the cause of a potential or actual non-compliance or other undesirable situation. (Article 2.67 of the Regulation)
Reminder	Any measure aimed at obtaining the return of a device that has already been made available to the end user. (Article 2.62 of the Regulation)
Complaint	Written, electronic or verbal communication of deficiencies relating to the identity, quality, durability, reliability, fitness for purpose, safety or performance of a medical device that is no longer under the control of the organisation or relating to a service that affects the performance of such medical device.
Withdrawal	Any measure to prevent a device in the supply chain from remaining available on the market. (Article 2.63 of the Regulation)

The definitions set out in the General Terms and Conditions of Subscription apply to this Quality Assurance Contract, of which it constitutes an independent appendix, which may be the subject of an amendment between the Parties.

Acronyms

RMA	Return Merchandise Authorization
ANSM	National Agency for the Safety of Medicines and Health Products
GDPR	General Data Protection Regulation

Reference documents

Reference	Title
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)
Regulation (UE) 2016/679	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

1. Purpose of the Quality Assurance Agreement

This Quality Assurance Contract defines the CLIENT's obligations concerning the qualitative aspects relating to the use and provision of the BORA CARE Solution on French territory, as well as to the Accessories, Materials and associated Services. It forms an integral part of the Subscription Contract and the General Terms and Conditions of Subscription of which it is an appendix.

In addition, the CLIENT undertakes to adopt all quality assurance measures required to obtain the level of quality contractually agreed and/or required by the regulations in force.

In particular, the CLIENT shall comply with the provisions of the Public Health Code (CSP) and Regulation (EU) 2017/745 governing the provision of medical devices and the obligations relating thereto.

The present Quality Assurance Contract applies without prejudice to the cases in which the CLIENT shall be considered as having to fulfil the obligations of the Manufacturer of the device, BiOSENCY, in application of Article 16 of Regulation (EU) 2017/745.

2. Duration of validity

The Quality Assurance Agreement shall remain in force until complete return by the CLIENT of all BORA BAND Wristbands, Materials and Accessories to BiOSENCY and until the end of the rights of use of the BORA CONNECT Platform.

3. Training

Upon signature of the Subscription Contract, initial training is provided by BiOSENCY to the CLIENT. An e-learning tool is also made available to the CLIENT by BiOSENCY.

The CLIENT determines which members of its personnel in charge of the provision and/or use of the BORA CARE Solution shall follow the training and documents the training undertaken.

All personnel with responsibility for a specific task must have the required training and/or experience to meet the requirements of that function.
Records of staff training shall be retained by CLIENT.

4. Service

4.1 Installation

All installation processes and procedures applied shall follow the procedures described in the current user manuals for the BORA CARE Solution.
CLIENT agrees to provide Patients with the entire "Hardware Kit" consisting of the BORA BAND wristbands, hardware and accessories listed in the Special Terms and Conditions of the Subscription Agreement and the accompanying documentation, including the current Patient User Guide.
Documentation relating to the installation and use of the BORA CARE Solution must be retained by the CLIENT. The documentation for each installation shall contain at least the following documents and information :

- Item number
- Serial number
- Date of installation
- Name and surname of the installer

4.2 Cleaning

After use, the CLIENT must clean the used device before transferring it to a new Patient. All cleaning processes and procedures applied must follow the procedures described in the applicable instructions for use. These cleaning processes and procedures must be recorded, documented and communicated to BiOSENCY upon request.

The textil straps are consumable accessories. They should be changed between patients and discarded and should not be returned to BiOSENCY.

4.3 Traceability

All elements supplied, BORA BANDS, Accessories and Materials must be traceable from their delivery to the CLIENT to their provision to the Patients, their return by the Patients to the CLIENT and their return by the CLIENT to BiOSENCY, and through all phases of installation with the exception of consumable single-use accessories which must not be returned to BiOSENCY. All these elements are subject to traceability, notably by order number, serial number, installation date, date of availability, return date, cleaning.

In accordance with Article 25 of Regulation (EU) 2017/745, and with the aim of achieving an appropriate level of traceability of devices, the CLIENT must implement all necessary measures to be able to identify for a period of at least ten (10) years from the last device covered by the declaration of conformity being made available on the market, any economic operator, any health care institution and any health care professional to whom it has directly supplied the device.

The CLIENT undertakes to communicate this information to any competent authority that may request it.

4.4 Transport and storage

Throughout the period during which the devices are under the responsibility of the CLIENT, the CLIENT undertakes to respect the conditions of storage and transport foreseen by BiOSENCY and indicated in the accompanying documentation so that the conformity of the devices to the general safety and performance requirements is not compromised.

These conditions must be respected by the CLIENT for the devices it makes available on the market as well as for the devices in its possession that are subject to withdrawal or recall.

The CLIENT's responsibility for compliance with the conditions of transport and storage of the devices shall commence on the date of delivery of the devices to the CLIENT.
En cas de modification des conditions de transport et de stockage des dispositifs, BiOSENCY s’engage à en informer le CLIENT le plus tôt possible et au plus tard lors de la première commande du CLIENT suivant la modification.

4.5 Support management

The CLIENT undertakes to inform the Users of the means of contact they have at their disposal to contact the CLIENT for assistance. The means of communication of this information must be communicated to BiOSENCY and validated by BiOSENCY. A specific insert is available on the Quick Start Guide for the CLIENT to label with his contact information.

The CLIENT is the point of entry for BiOSENCY's CLIENT support.

Within the framework of the support, the CLIENT takes charge of the requests, collects all information necessary for the treatment of the request and evaluates if the request corresponds to a procedure established in the documentation or training provided by BiOSENCY (e.g. in the user's manual, the platform's user documentation, the online training modules).

The CLIENT's support provided to the Patients shall cover in particular:
- The use of the BORA BAND
- The use of the BORA CONNECT Platform

If this is the case, the procedure is carried out by the CLIENT. If not, the request is escalated to BiOSENCY's support by means of dedicated communication supports. In this respect, the CLIENT undertakes not to transmit to BiOSENCY the identity and/or health data of the Patient.

4.6 Feedback from users

The CLIENT undertakes to synthesize the feedback from users in a pseudonymized manner, whether positive or negative, and to present it monthly to BiOSENCY. This feedback includes in particular the categories of assistance interventions from the CLIENT to the user.

5. Management of deviations

5.1 Non-conforming products

The CLIENT undertakes to install the BORA BAND Wristbands, Materials and Accessories in accordance with the required specifications and the accompanying documentation provided.

The CLIENT shall immediately transmit to BiOSENCY any non-conformity, any complaint and any report from health professionals, patients or users concerning alleged incidents related to the device it has provided. It notifies this information within a maximum of two (2) days by means of dedicated communication media.

As a general rule, a non-conformity leads to the CLIENT stopping using
- either of the BORA CONNECT Platform for the subscription concerned
- or the non-compliant Hardware or Accessory (and its replacement).

The CLIENT undertakes to follow the provisions set out in the instructions for use of the Equipment or Accessory concerned. If it is not possible to identify or eliminate the cause, the CLIENT shall call BiOSENCY's Support Service who will inform him/her of the actions to be taken.

The CLIENT undertakes to immediately and personally inform the BiOSENCY Support Service of any undesirable events encountered in relation to the installation of the Materials or Accessories and to follow the recommendations made by the latter.

5.2 Products return

The CLIENT agrees to follow the procedures for the return of Hardware in force, as communicated by BiOSENCY. The CLIENT shall return any Hardware or Accessory (except single-use consumables) after having received a return number from BiOSENCY. It shall use the RMA form provided by BiOSENCY (FOR-04-01-03). The CLIENT undertakes to clean any Material or Accessory before its return to BiOSENCY, in accordance with part 3.3 Cleaning process.

5.3 Complaint Management

The analysis and management of the CLIENT's complaints are the responsibility of BiOSENCY. The CLIENT grants BiOSENCY the right to assist in the investigation through qualified personnel in all aspects required to eliminate potential risks to the Patients.

The CLIENT shall provide, without delay and at the latest within two (2) working days from the receipt of the request, any information requested by BiOSENCY in order to allow the investigation of the claims to be carried out.

6. Monitoring, vigilance, traceability

The CLIENT who makes the BORA CARE Solution available on the market, up to the stage of its commissioning, within the meaning of Regulation (EU) No. 2017/745, is a distributor within the meaning of this same Regulation.

In such a case, the CLIENT therefore undertakes to comply with the obligations placed on distributors of medical devices, in particular the obligations referred to in Article 14 of Regulation (EU) 2017/745, regarding traceability, market surveillance and information to the competent authorities. As examples :

- The CLIENT who receives a complaint or report from a Health Professional or a Patient related or likely to be related to a device it has made available must immediately transmit this information to BiOSENCY, within a maximum period of forty-eight (48) hours ;

- In case of a serious incident identified by the CLIENT, the CLIENT shall inform BiOSENCY immediately and within a maximum of twenty-four (24) hours;

- If the CLIENT considers or has reason to believe that a device it has made available does not comply with the requirements of Regulation (EU) 2017/745, it shall immediately inform BiOSENCY, and cooperate with BiOSENCY as well as with the competent authority to ensure that corrective measures are taken ;

- Where a device presents a serious risk, the CLIENT shall immediately inform the competent authority;

- The CLIENT shall keep a register of complaints, non-compliant devices and recalls and withdrawals. The CLIENT keeps a register of complaints, non-conforming devices and recalls and withdrawals. It keeps BiOSENCY informed of these activities and provides it, at its request, with any information to enable it to investigate these complaints;

- The CLIENT shall cooperate with BiOSENCY and the competent authorities to implement any corrective measures that may be required. The CLIENT is also bound in particular, under Regulation (EU) 2017/745, to an obligation of diligence, cooperation with the authorities and confidentiality.

The notifications to BiOSENCY referred to above must be made to the persons referred to in Article 14 of this contract.

The CLIENT also undertakes to comply with the provisions of the Public Health Code regarding medical devices.

7. Preventive and corrective measures

The CLIENT's organization includes, procedures ensuring that the CLIENT is informed of any corrective action taken by BiOSENCY in relation to the device in order to resolve safety issues or to bring the Equipment into compliance with Regulation (EU) 2017/745.

If BiOSENCY is at the initiative of corrective or preventive measures to be implemented for Materials that the CLIENT has made available on the market or that it is about to make available on the market within the framework of the present contract, the CLIENT undertakes to cooperate with BiOSENCY as well as with the ANSM or other competent authority so that these measures are implemented as soon as possible.

If the ANSM initiates corrective or preventive measures to be implemented for Materials that the CLIENT has made available on the market, the CLIENT undertakes to immediately inform BiOSENCY, then to cooperate with the latter as well as with the competent authorities concerned so that these measures are implemented as soon as possible.

If the CLIENT notices a non-conformity in a device that it has made available on the market or that it is about to make available on the market, it shall immediately inform BiOSENCY, but shall not implement any corrective or preventive action without prior written agreement from BiOSENCY or express request from a competent authority, with the exception of a possible quarantine of the devices that it has not yet made available on the market.

The CLIENT undertakes not to undertake any investigation on the device in its possession that is likely to modify it to the point of compromising BiOSENCY's investigations.

7.1 Reminder

BiOSENCY assigns a serial number to the manufactured Materials. The CLIENT shall ensure traceability in accordance with part 4.3 Traceability.

In case of a recall, the CLIENT undertakes to make investigations in order to establish the list of Users potentially concerned by the failure of the recalled Equipment and/or the update of mobile applications, and to communicate to them the relevant information related to the recall.

7.2 Safety notices

In case of communication of a security notice from BiOSENCY to the CLIENT, the CLIENT commits to send an acknowledgement of receipt to BiOSENCY, and to distribute the security notice to the concerned Users.

8. Integrity of the Material

The CLIENT is not allowed to damage the integrity of the Material, including any modification of the packaging elements, deconditioning/repackaging, and modification, including translation, or addition of labels or instructions for use that would be likely to modify the texts present on or accompanying the Material.

The present clause does not apply to the addition by the CLIENT of its contact information on the Material in conditions that do not alter the Material in question or its packaging and that do not lead to confusion with the indication of the status and contact information of BiOSENCY. Furthermore, the CLIENT undertakes not to conceal any information appearing on the BiOSENCY label if it adds elements concerning its identification on the Material.

9. Confidentiality

The Parties undertake to respect, for a duration and under conditions in accordance with the applicable regulations, the confidentiality of information and data obtained in the execution of their tasks and in particular in the framework of the present mandate so as to protect:

- personal data ;
- confidential information of a commercial nature and business secrets of natural or legal persons, including intellectual property rights, unless the public interest justifies disclosure;
- law enforcement, in particular with regard to inspections, investigations or audits.

10. Subcontracting

Prior to the conclusion of the Subscription Contract, the CLIENT undertakes to inform BiOSENCY in case of subcontracting of one or more of the obligations applicable to it under Regulation (EU) 2017/745. The CLIENT undertakes not to subcontract any new obligations arising from Regulation (EU) 2017/745 after the conclusion of the Subscription Contract without prior written agreement from BiOSENCY. The CLIENT undertakes to transpose in its relations with its subcontractors the requirements arising from Regulation (EU) 2017/745 and those that BiOSENCY has imposed on it in the framework of the Subscription Contract. The CLIENT undertakes to provide BiOSENCY, at its request, with any element allowing to demonstrate that it ensures the respect of these requirements by its subcontractors.

11. Information and promotional media

The CLIENT is prohibited from disseminating any claim contrary to Article 7 of the Regulation and any claim other than those transmitted or previously validated by BiOSENCY whatever the medium used. According to Article 7 of Regulation (EU) 2017/745, the following are prohibited:

- which attribute to the device functions and properties that it does not have;
- which give a misleading impression of treatment or diagnosis, or of functions or properties which are not those of the device in question;

- which fail to inform the user or patient of a probable risk associated with the use of the device in accordance with its intended purpose;
- which suggest uses of the device other than those for which the conformity assessment was carried out.

12. Audit

Upon simple request of BiOSENCY, audits by BiOSENCY may be carried out on the CLIENT's premises with a ten (10) calendar day notice period, or by a third party (notified body or competent authority) with or without notice period, and accessibility to the premises and documents related to the activities of this contract shall be guaranteed. When BiOSENCY is audited or inspected (with or without notice), BiOSENCY shall inform the CLIENT as soon as BiOSENCY knows the dates and the CLIENT undertakes to communicate within twenty-four (24) hours the documents/records that may be required.

13. Archiving

The documents and records relating to the installation, training and cleaning of the Material must be kept for five (5) years by the CLIENT. At the end of this period, the CLIENT shall agree with BiOSENCY on what is to be done with these documents, so that BiOSENCY has the possibility to continue archiving them.

In case of termination of the collaboration, the CLIENT undertakes to provide the documents immediately upon request, and to respond to complaints and requests for information from the authorities in a timely and correct manner. Alternatively, the CLIENT undertakes to hand over to BiOSENCY the corresponding installation documents for archiving purposes.

The CLIENT shall archive the documents related to traceability for the duration defined in part 4.3 Traceability.

14. Notifications

The notifications mentioned in the present Quality Assurance Contract, in particular at the end of the vigilance, surveillance, conformity, must be made to BiOSENCY through the following means of contact
Telephone: 0 800 910 073, Email: qar@biosency.com.

15. Modifications - Amendments

The present Quality Assurance Contract constitutes an Annex to the General Subscription Conditions. It may be subject to modification at the request of one or other of the Parties, which the Parties undertake to formalise and negotiate in good faith, independently of the General Subscription Conditions to which this Quality Assurance Contract is attached.