ANNEX – GENERAL TERMS

MEDICAL DEVICE REGULATION – DISTRIBUTOR'S OBLIGATIONS & RESPONSIBILITIES

The Medical devices Regulation (EU) 2017/745 ("MDR"), applicable since 26 May 2021, replaced the Directive 93/42/EEC and introduced a significantly revised regulatory regime governing Medical devices.

This new regulation implies a substantial revision of the responsibilities of each actor in the distribution chain of Medical devices regarding their quality, regulatory and safety obligations.

As provided in Article 5.6 of the General Terms of AGUETTANT, the Distributor undertakes to comply with the MDR and in particular the provisions of the present note.

1. Definitions

The use of the terms listed below shall be understood as follows in accordance with Article 2 of the MDR:

Terms - Abbreviations	Definitions
Competent Authority (CA) or Regulatory Authority	Any governmental regulatory authority responsible for public health, conducting inspections, vigilance activities, granting marketing authorizations, health or tariff approvals, registration, import authorizations or other approvals required before the Product is tested, administered or placed on the market in a country.
Medical device (MD)	Any instrument, apparatus, equipment, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, in humans for one or more of the following specific medical purposes- diagnosis, prevention, monitoring, prediction, prognosis, treatment or mitigation of disease, - diagnosis, monitoring, treatment, mitigation of or compensation for injury or disability, - investigation, replacement or modification of an anatomical structure or function or of a physiological or pathological process or condition,- the communication of information by means of in vitro examination of samples from the human body, including donated organs, blood and tissue, the principal intended action of which in or on the human body is not obtained by pharmacological or immunological means or by metabolism, but the function of which may be assisted by such means. The following products shall also be deemed to be Medical devices: - Medical devices intended to control or assist conception- products specifically intended for the cleaning, disinfection or sterilization of the Medical devices referred to in Article 1(4) of the MDR and those referred to in the first subparagraph of this section.
Distributor	any natural or legal person in the supply chain, other than the manufacturer or importer, that makes a Medical device available on the market, until up to the point of putting into service.
Manufacturer	a natural or legal person who manufactures or refurbishes a Medical device or has a Medical device designed, manufactured or refurbished, and markets this Medical device under its name or brand.
Unique Medical device Identifier (UDI)	A series of numbers or letters created according to internationally accepted Medical device identification and coding standards, and which allows the formal identification of specific Medical devices on the market.
Incident	Any malfunction or alteration in the characteristics or performance of a Medical device made available on the market, including an error in use due to ergonomic features, as well as any defect in the information provided by the manufacturer and any undesirable side-effects.
CE conformity marking or CE marking	Marking by which a manufacturer indicates that a Medical device complies with the applicable provisions of the MDR and other Union harmonization legislation which provides for its affixing.

Commissioning	The stage at which a Medical device, other than a Medical device under investigation, is made available to the End User, being ready for first use on the Union market in accordance with its intended purpose.
Placing on the market	The first making available of a Medical device, other than an investigational Medical device , on the EU market.
User	Any health professional or lay person who uses a Medical device
EU Regulation 2017/745 or Regulation or MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical devices.
Directive 93/42/EEC or Medical device Directive or MDD	Medical device Directive as amended by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical devices.

2. The Distributor's due care

According to article 14.1 of the MDR, the Distributor, when making a Medical device available on the market, must act, within the framework of its activities, with the diligence required to respect the applicable requirements. He also undertakes to always have at his disposal the human (qualified and available personnel) and material (infrastructure, tools, etc.) resources necessary to carry out these activities and to comply with these obligations.

The Distributor undertakes to inform the Manufacturer of any regulatory requirements specific to the Member State in which it makes the Medical device available on the market, related to the provision and Commissioning of the Medical device as well as to material safety formalities.

The Distributor undertakes to carry out any administrative formality relating to the Medical device and laid down to the Manufacturer by a specific regulation of the Member State in which it makes the Medical device available on the market upon written request or after written authorization from the Manufacturer.

3. Pre-marketing checks and notification in case of non-conformity or post-marketing reports

a. ***Pre-marketing*** verification

According to Article 14.2 of the MDR, the Distributor undertakes to make available on the EU market only Medical devices that comply with Regulation (EU) 2017/745 and the applicable national regulations.

To this end and in accordance with Regulation (EU) 2017/745, the Distributor undertakes to verify that the following conditions are met before making a Medical device available on the market:

- The Medical device has been CE marked and the EU Declaration of Conformity for the Medical device has been issued,
- The Medical device is accompanied by instructions for use and/or labelling in accordance with the applicable regulations and in the language of the country in which it is made available,
- The Manufacturer has assigned a Unique Medical device Identifier to the Medical device in accordance with the regulations in force.

In accordance with Regulation (EU) 2017/745, if the Distributor considers or has reason to believe that the Medical device does not comply with the requirements of that Regulation, he shall not make the Medical device available on the market and shall inform the Manufacturer thereof within a maximum of two (2) working days.

The Distributor shall not make the Medical device available on the market until it has been brought into compliance.

Where the Distributor considers or has reason to believe that the Medical device presents a serious risk or is a falsified Medical device, he shall also inform the Competent Authority of the Member State in which he is established within one (1) working day and the Manufacturer in accordance with Article 5 of this the present

annex.

b. Notifications of non-compliance or *post-marketing* alerts

According to Article 14.4 of the MDR, a Distributor who considers or has reason to believe that a Medical device is not in compliance with the MDR shall inform the Manufacturer within a maximum of two (2) working days after becoming aware of it. The Distributor shall cooperate with the Manufacturer and the Competent Authorities to ensure that the necessary corrective action is taken to bring the Medical device into compliance, withdraw it or recall it.

Where the Distributor considers or has reason to believe that the Medical device presents a serious risk or is a falsified Medical device, the Distributor shall immediately, i.e., within one (1) working day, inform the Competent Authorities of the Member States in which he has made the Medical device available and specify, in particular, the case of non-compliance and any corrective measures taken.

The Distributor must also inform the Manufacturer in accordance with Article 5 of this Present annex.

4. Transport & storage

According to Article 14.3. of the MDR, throughout the period during which the Medical devices are under the responsibility of the Distributor, the latter undertakes to respect the storage and transport conditions provided by the Manufacturer and indicated in the specifications so that the conformity of the Medical devices with the general safety and performance requirements is not compromised. These conditions must be respected by the Distributor for the Medical devices it makes available on the market as well as for the Medical devices in its possession that are subject to withdrawal or recall.

5. Register of complaints, incidents, and non-conformities

According to Section 14.5 of the MDR, the Distributor shall maintain a record of complaints, Incidents, and non-conformances (hereinafter the "Record"), non-conforming Medical devices and recalls and withdrawals, and shall keep the Manufacturer informed of these follow-up activities. The Distributor shall provide the Manufacturer with the Register of its follow-up activities upon request by the Manufacturer, within five (5) days.

The Distributor shall provide, without delay and no later than one (1) working day after receipt of the request, any information requested by the Manufacturer to enable the investigation of the claim.

The Distributor shall immediately notify the Manufacturer of any non-compliance, complaints and reports from healthcare professionals, patients or Users relating to suspected Incidents involving the Medical device it has made available on the EU market. The Manufacturer shall send this information within a maximum of two (2) working days by e-mail to the following address: reclamations@aguettant.fr.

In the event of a serious risk or threat identified in the course of such a claim or report, the Distributor shall inform the Manufacturer within one (1) working day at the following address: materiovigilance@aguettant.fr.

6. Provision of samples to Competent Authorities

Under Article 14.6 of the MDR, in the context of any measures taken to eliminate or mitigate the risks presented by the Medical device made available on the market by the Distributor, the Distributor shall cooperate with the Competent Authorities in the implementation of these measures.

In this regard, any sample supplied to a Competent Authority at its request shall be provided by the Distributor as soon as possible.

In the event of a request for access to a Medical device by a Competent Authority, the Distributor undertakes to do everything possible to allow such access within fifteen (15) working days.

7. Cascade distribution

In case of sale **by the Distributor** of a Medical device to an operator with a distributor status as defined in Regulation (EU) 2017/745, the Distributor will undertake to transpose in its relations with this operator the requirements that the Manufacturer has imposed on it in this Information Note concerning:

- transport and storage conditions,
- pre-marketing checks on Medical devices,
- the identification and traceability of Medical devices,
- vigilance and notifications,
- cooperation with economic operators in the distribution chain,
- cooperation with the Competent Authorities and notified bodies,
- confidentiality,
- the information accompanying the Medical devices (instructions for use and/or labelling according to the risk class of the Medical device, etc.)
- advertising or other materials relating to Medical devices,
- the modification of packaging elements.

8. Subcontracting

The Distributor undertakes to inform the Manufacturer in case of subcontracting of one or more of its obligations under Regulation (EU) 2017/745. The Distributor undertakes not to subcontract any new obligations arising from Regulation (EU) 2017/745 without the prior written consent of the Manufacturer.

The Distributor undertakes to transpose into its relations with its subcontractors the requirements arising from Regulation (EU) 2017/745. The Distributor agrees to provide the Manufacturer, at the Manufacturer's request, with evidence that the Manufacturer has ensured that its subcontractors comply with these requirements.

9. Labelling and instructions

According to Article 10.11 and 14.2 of the MDR, the Distributor undertakes to make the Medical devices available on the market with instructions for use and/or labelling according to the risk class of the Medical device in the official language(s) defined by the country concerned. These elements must have been provided or validated in writing by the Manufacturer.

10. Integrity of the Medical device

The Distributor is not permitted to tamper with the integrity of the Medical device, including any modification of the packaging elements, unpacking/repacking, and modification, including translation, or addition of labelling or instructions for use that would alter the text on or accompanying the product.

Any change envisaged by the Distributor concerning the label, the instructions for use or the packaging of the product must be made in accordance with the conditions indicated in Article 16 section 2 of Regulation (EU) 2017/745.

This clause does not apply to the addition of the Distributor's contact information to the Medical device in a manner that does not alter the Medical device or its packaging and is not confusing with the status and contact information of the Manufacturer. Furthermore, the Distributor agrees not to conceal any information on the Manufacturer's label if he adds his identification details to the Medical device.

If the Distributor carries out modifications to a Medical device which are not considered likely to affect its conformity with the applicable requirements and which are necessary for the marketing of the Medical device in the Member State concerned, he shall indicate on the Medical device or, if this is not possible, on its packaging or in a document accompanying the Medical device, the activity carried out, as well as his name, company name or registered trade mark, registered office and the address at which he can be contacted in order to be able to establish his location.

At least twenty-eight (28) days before the relabeled or repackaged Medical device is made available on the market, the Distributor shall also inform the Manufacturer and the Competent Authority of the Member State in which he intends to make the Medical device available of the intention to make the relabeled or repackaged Medical device available, and shall provide the Manufacturer and the Competent Authority, on request, with a copy or mock-up of the relabeled or repackaged Medical device, together with any translated label and instructions for use. Within the same twenty-eight (28) day period, the Distributor shall provide the Competent Authority with a certificate, issued by a notified body designated for the type of Medical devices subject to the said modifications, attesting that the Distributor's quality management system complies with the requirements of the MDR.

11. Information or promotional materials

The Distributor is prohibited from making any claim contrary to Article 7 of the MDR and/or any claim other than those made or previously validated by the Manufacturer, regardless of the medium used.

The Distributor shall ensure that any information or promotional material relating to the Medical devices complies with the regulations applicable in the country in which it makes the Medical devices available on the market.

In the event that the Manufacturer modifies the information or promotional material, the Distributor will adapt the information or promotional material within a period of time to be agreed between the Parties after the Manufacturer's notification. The costs of the modifications to the information or promotional material made necessary by the regulations will be borne by the Distributor.

12. Preventive and corrective measures

Distributor control includes procedures to ensure that the Distributor is informed of any corrective action taken by the Manufacturer in relation to the Medical device to resolve safety issues or to bring the Medical device into compliance with the MDR.

If the Manufacturer initiates corrective or preventive measures to be implemented for Medical devices that the Distributor has made available on the market or is about to make available on the market in the framework of the Present annex, the Distributor undertakes to **cooperate** with the Manufacturer as well as with the relevant economic operators and Competent Authorities to ensure that these measures are implemented as soon as possible.

If a Competent Authority initiates corrective or preventive measures to be implemented for Medical devices that the Distributor has made available on the market, the Distributor undertakes to **inform** the Manufacturer immediately and then to **cooperate** with the Manufacturer and the economic operators and Competent Authorities concerned to ensure that these measures are implemented as soon as possible.

If the Distributor notices a non-conformity on a Medical device that he has made available on the market or that he is about to make available on the market, he **informs** the Manufacturer and, if necessary and at the request of the Manufacturer, the Competent Authority concerned, in accordance with the Information Note, but does not implement **any corrective or preventive action without the prior written agreement of the Manufacturer** or the express request of a Competent Authority, with the exception of a possible quarantine of the Medical devices that he has not yet made available on the market

The Distributor agrees not to undertake any investigation of the Medical device in his possession that would alter it in a way that would compromise the Manufacturer's investigations.

13. Traceability

In accordance with Article 25 of the MDR and with the aim of achieving an appropriate level of traceability of Medical devices, the Manufacturer and Distributor must implement all the necessary measures to be able to identify for a period of at least ten (10) years from the Placing on the market of the last Medical device covered by the EU declaration of conformity any economic operator, any health care establishment and any health care professional to whom it has directly supplied the Medical device.

They undertake to communicate this information to any Competent Authority that requests it.