This quality charter for the distribution of medical devices (hereinafter referred to as the "**Charter**") applies to any partner who is a Distributor (as defined below) of the Products (as defined below) marketed by Cleanis, Laboratoires Innothera, Laboratoire Innotech International and/or Gibaud (hereinafter referred to as the "**Manufacturer**") and having concluded an agreement with the Manufacturer.

In accordance with an agreement and/or the Manufacturer's general conditions of sale (hereinafter referred to as the "**Agreement**"), the Manufacturer entrusts the Distributor with the distribution of its Products. As such, the Parties must comply with the obligations imposed by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 relating to medical devices (hereinafter referred to as the "**MDR**") and with all other laws and regulations of the Applicable territory.

1. Definitions

For the purposes of the Charter, the Parties agree that all terms beginning with a capital letter have the meaning given to them in this article or, failing that, in the Agreement. Where appropriate, the provisions of the Agreement supplement the provisions of the Charter. However, in the event of a contradiction between the terms defined in this article and those defined in the Agreement, the definitions in this article shall prevail.

"**Field Safety Corrective Action or FSCA"** means any action taken by the Manufacturer to reduce a risk of death or serious deterioration in the state of health of patients, users or third parties associated with the use of a Device which has already been Placed on the Market. Customers and/or users are informed of a Field Safety Corrective Action (or FSCA) by means of a Field Safety Notice – FSN.
An FSCA may include a Device modification, Device exchange, Device Recall, recommendations for use, recommendations for patient follow-up, etc. (recommendations from the European Commission (MEDDEV)).

"**Field Safety Notice or FSN**" means any communication sent by the Manufacturer to users or customers in relation to a Field Safety Corrective Action.

"**Distributor"** means any natural or legal person in the supply chain, other than the Manufacturer, who distributes the Product in accordance with article 2.34 of the MDR.

"**Manufacturer**" means the natural or legal person who manufactures or refurbishes the Product or has the Product designed, manufactured or refurbished, and markets this Product under its name or under its brand in accordance with article 2.30 of the MDR.

"**Incident**" means any malfunction or deterioration in the characteristics or performance of a Device Made Available on the Market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the Manufacturer and any undesirable side effect in accordance with article 2.64 of the MDR.

"**Serious incident**" means any incident that directly or indirectly led, might have led or might lead to: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's a state of health; c) a serious public health threat in accordance with article 2.65 of the MDR.

"**Made Available on the Market**" or "**Making Available on the Market**" means any supply of a Product, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge in accordance with Article 2.27 of the MDR.

"**Placed on the Market**" means the first making available of a Device, other than an investigational device, on the Union market in accordance with Article 2.28 of the MDR.

"**Parties**" means both the Manufacturer and the Distributor.

"**Product(s)" or "Device(s)**" means the Manufacturer's product(s) distributed by the Distributor under the Agreement that falls within the definition of Article 2.1 of the MDR, that is, any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the medical purposes specified in article 2.1 of the MDR and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such mean. The following products are also deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for cleaning, disinfection or sterilization.

"**Recall**" means any measure aimed at achieving the return of a Device that has already been made available to the end user in accordance with article 2.62 of the MDR.

"**Withdrawal**" means any measure aimed at preventing a Device in the supply chain from being further Made Available on the Market in accordance with Article 2.63 of the MDR.

"**Alteration**" means any action on a device to bring it into conformity with requirements.

"**Territory**" means the country or countries in which the Products are distributed by the Distributor.

2. Obligations of the Distributor

a) General obligations

The Distributor undertakes to carry out the activities and to comply with the obligations deriving from the Charter with due diligence. The Distributor also undertakes to have at all times the human resources (qualified and available staff) and materials (infrastructure, tools, etc.) required for carrying out these activities and meeting these obligations.

The Distributor undertakes to communicate to the Manufacturer, at the latter's request, any element enabling the Manufacturer to demonstrate compliance with the requirements applicable under the regulations in force.

b) Checks before being Made available on the Market

The Distributor undertakes to check that the following conditions are met before the Device is made available on the Market:

- the Device bears the CE marking and the EU declaration of conformity of the Device has been drawn up;
- the Device is accompanied by a label and instructions for use in accordance with applicable regulations;
- the Manufacturer is identified and has indicated his contact details on the Device, its packaging or any other accompanying document; and
- the Manufacturer has assigned a unique identifier to the Device.

c) Notification in the event of non-compliance and/or reports

The Distributor undertakes to inform the Manufacturer of any incident as defined in article 2.64 of the MDR (in particular any non-compliance, any complaint and any report, including cases of vigilance) concerning a Product that the Distributor (i) intends to distribute or (ii) has distributed in the Territory. The Distributor must report the information by email to the following address: INFORMATION.VIGILANCE@innothera.com.

The report must be made:
- Without delay for a serious incident;
- Within 24 hours for other incidents.

When the non-conformity is identified before the Device is Made Available on the Market by the Distributor, the latter must report it to the Manufacturer and only make the Device available on the Market after the Device has been brought into conformity by the Manufacturer.
When the Distributor has Made the Device Available on the Market, these reports must be made immediately, that is to say as soon as the Distributor becomes aware of the non-compliance, the complaint or the report.
In the event of Notifications for non-compliance and/or reports, the distributor undertakes to transmit all communications to the end customer without making any changes to them.

d) Complaints register

The Distributor undertakes to (i) keep a register of complaints, of non-conforming Devices and Recalls and Withdrawals, (ii) to provide the Manufacturer with any information on request, and to (iii) keep the latter informed of all monitoring activities.

e) Transport and storage

Throughout the period during which the Devices are under their respective responsibilities, the Manufacturer and the Distributor undertake to comply with the storage, transport and handling conditions provided for by the Manufacturer and indicated in the accompanying documentation (labelling, instructions). These conditions must be respected by the Distributor for the Devices that the latter Makes Available on the Market as well as for the Devices subject to a Withdrawal or a Recall.

f) Traceability

The Distributor undertakes to ensure the traceability of the Devices that are Made Available on the Market for a period of at least 10 years from the Placing on the Market of the last Device covered by the EU declaration of conformity in order to:
- identify any economic operator, any health establishment and any health professional to whom the Device has been directly supplied;
- unambiguously recall any Device if necessary.

g) Corrective Safety Action and Recall

The Distributor undertakes to assist the Manufacturer for all Device Recall actions as well as for all Corrective Safety Actions if necessary.

h) Audit

Where applicable, the Distributor undertakes to receive the Manufacturer in the framework of audits relating to the Devices Made Available on the market subject to one (1) month notice, unless otherwise required by law, sent in writing to the Distributor.

i) Subcontracting

If the Distributor calls on one or more subcontractors, the Distributor undertakes to transpose into its relations with the subcontractor(s) the requirements deriving from the MDR and the Charter imposed by the Manufacturer.
At all times, the Distributor must demonstrate that (i) it exercises effective control over the subcontractor(s) and (ii) the subcontractor(s) comply with the obligations laid down in the Charter.

j) Product conformity

The Distributor must Make Products Available on the Market with labels in the official language(s) of the relevant country. The labelling must have been supplied or approved by the Manufacturer.

The Distributor is not authorized to infringe the physical integrity of the Product, which includes any modification of the packaging items, any unpacking or repackaging, and any translation, or addition of labels or instructions for use which would be likely to modify the texts present on the Product or accompanying it.

This article does not apply to the addition to the Device, by the Distributor, of its contact details under conditions which do not alter the Device or its packaging and which do not lead to confusion about the Manufacturer's status and contact details. Furthermore, the Distributor undertakes not to conceal any information appearing on the Device in the event information is added concerning its identification.

This article does not apply to any alterations expressly requested by the Manufacturer from the Distributor.

k) Information or advertising material

The Distributor must refrain from circulating any allegation other than those transmitted by the Manufacturer, regardless of the medium used.

In the event of the sale of a Device to another operator with a Distributor status within the meaning of the MDR (hereinafter referred to as "**Cascade Distribution**"), the Direct Distributor undertakes to transmit to its sub-distributor only information or advertising material (except price offers) that it itself is authorized to transmit and that has been communicated or validated by the Manufacturer.

l) Confidentiality

The Parties undertake to respect, for a period and under conditions in keeping with applicable regulations, the confidentiality of information and data obtained in the performance of their tasks and in particular within the framework of the Charter so as to protect:

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

m) Cascade distribution

In the event of Cascade Distribution, the Distributor undertakes to transpose into its relations with its sub-distributor the requirements imposed by the Manufacturer on the Distributor in the Charter concerning:

- transport and storage conditions,
- the checks prior to the Making Available on the Market of the Devices,
- vigilance, reporting and associated actions,
- traceability,
- subcontracting,
- cooperation with economic operators in the distribution chain,
- cooperation with the competent authorities,
- confidentiality,
- the information accompanying the Devices (label, instructions for use, etc.)
- information and advertising materials for the Devices, and
- packaging item modifications.