PARC DES FORGES – 8 RUE LOUISE MICHEL – 67200 STRASBOURG – France
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Distribution contract
Quality and Vigilance related to medical devices

Subscribed between the company:

COMED SAS
Parc des Forges – 8 rue Louise Michel
67200 STRASBOURG – France

Recorded in the Register of Commerce at Strasbourg with the number 323 192 260

on the one hand, hereinafter referred to as "Supplier" and the company:

on the other hand, hereinafter referred to as "Distributor".

The purpose of this contract is to define the obligations of both the parties in order to comply with European regulatory requirements for the marketing of medical devices (Directive 93/42/CEE and the regulation 2017/745).

1. Within the framework of the vigilance system for the medical devices, the distributor undertakes to inform the supplier, if it has the knowledge of an incident likely to be falling within the scope of the vigilance system. In case of a serious incident, following the scale of authority of the country in question, the distributor shall, without any delay, communicate this incident to the authorities of the country in question and to the manufacturer, while keeping the supplier informed. If the supplier receives an alert concerning a medical device for which it is not the manufacturer, it shall immediately forward this alert to the manufacturer.

2. The distributor shall provide to the supplier or the manufacturer all the elements collected through its own customers that may have an impact on the product quality and allow for a proper analysis of the incident. All observations shall be notified to the supplier.

3. In the event of an incident or recall of a product sent by the manufacturer, the supplier informs the distributor who undertakes without delay, the recall and detention of the recalled or blocked products, in accordance with the manufacturer's request. According to the general terms and conditions of sale and the remarks on the invoices, the distributor must be able to recall or block all the products delivered to it, which are impacted by the recall. The supplier will notify the distributor of the procedures to be followed for such recalled products by following the requirements of the manufacturer.

4. The supplier's invoices shall indicate which devices are traceable; it is the distributor's responsibility to be able to trace and retrieve this type of device and if necessary to make contact with the user to warn it of an incident or to notify it of the planned recall procedure. The cost of recall between the distributor and his client shall be borne by the distributor who expressly undertakes to comply with this cost obligation. The fact of purchasing a traceable product from the supplier is recognition of this commitment.

5. The quality records must be kept for 10 years by the distributor, who undertakes to transmit all its records to the supplier, in the event of termination or change of activity.

6. Quality records include, but are not limited to: customer complaints, incidents, the elements enabling the traceability of the product, the requests for explanation of the product, after-sales service returns carried out at the distributor's end, the defective parts and general comments from customers on the supplier's products.

7. Commercial documentation, as well as, supporting documents, such as the operating procedure provided by the manufacturer, statutory labeling, and technical data cannot be changed or modified by the distributor. The Manufacturer and the supplier cannot be held responsible otherwise for any change in the content of the documents and labeling.

8. The distributor undertakes not to make any changes to the products, whether it is on the device itself or on its packaging or labeling.

9. This contract is valid on the territory where the distributor has its head office or on the first point of sale where it was carried out.

10. For the countries outside France, the distributor undertakes to ensure compliance over its territory of the devices, in accordance with the regulations in force. Particularly for the translation of commercial documents and operating procedure. The Manufacturer and the supplier cannot be held responsible for any bad translation.

11. In case of a change of status of the distributor's certification, it is the distributor's responsibility to notify the Manufacturer.

12. If the distributor resells the supplier's devices to another distributor, it undertakes to transmit all the obligations of this contract and keep a copy of the contract, which may be claimed by the supplier.

Signed at Strasbourg on

For the supplier:	*For the distributor:*
Name, first name:	Name, first name:
Position:	Position:
Signature :	Signature :

You can find these contractual conditions on our website www.comed.fr in the quality tab.