Distributor Agreement

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Distributor Agreement

I. Distributor Agreement between

This agreement is between Cantor + Nissel and

II. Scope

The purpose of this document is to define the obligations of distributors in order to comply with the MDR 2017/745 which starts on the 26th May 2021.

Note: This agreement does not define purchasing, ordering, delivery, returns or pricing for either party.

Note: This agreement does not define the specifications of the covered medical device.

III. Definitions according to the MDR 2017/745

'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished and markets that device under its name or trade mark;

'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulation;

'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

'user' means any healthcare professional or lay person who uses a device;

'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

'recall' means any measure aimed at achieving the return of a device that has already been made available to the end users

'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market;

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IV. Article 14 General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised

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representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device. Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

V. Termination of agreement

This agreement is valid from 3 years thereafter the date both parties have signed the agreement. Either party can terminate this agreement, by thirty (30) days' prior notice in writing.

VI. Signature

For the Manufacturer	**For the Distributor**
Date:	Date:
Name:	Name:
Position:	Position:
Signature	Signature