Cantor + Nissel Supplier Agreement Terms and Conditions

1. Scope of Agreement

This is an agreement between Cantor + Nissel Ltd as referred to as the “Purchaser”, and the supplier of purchased goods as referred to as the “Supplier”. This agreement shall apply to the goods as specified on the Purchase Order form.

By accepting this Purchase order, the supplier shall agree to the following stated terms and conditions.

2. Purpose

This agreement serves to define and establish the obligations and responsibilities of the Supplier and Purchaser related to the quality and regulatory standards required for all products and/or services delivered.

This agreement shall be valid from the date of acceptance of the Purchase Order by the supplier and shall remain valid until all obligations specified within this agreement have been fulfilled.

All information exchanged under this agreement shall be treated as commercially confidential by both parties.

3. Definitions

Legal Manufacturer - 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 trademark.

4. Responsibilities of the Purchaser

The purchaser is responsible for the approval of the supplier for the scope of products and / or service in relation to this agreement. Where the certification status of a supplier is leveraged in approval of the supplier, the purchaser shall state the requirement for this to be maintained.
The purchaser has the responsibility to provide sufficient information to the supplier via purchase order so that supplier can deliver a product or service in accordance with the purchasers requirements, and in accordance with any product specifications, regulatory requirements or standards that may apply.
The purchaser shall inspect goods or services provided by the supplier in a timely manner and shall formally notify the supplier of any non-conformity, or any other problematic issue, for the supplier’s attention and CAPA considerations.
The purchaser is responsible for the consideration to, and fulfilment of, regulatory requirements according to their undertaking as legal manufacturer of the associated end product medical devices placed upon the market.

5. Responsibilities of the Supplier

The supplier shall ensure they only accept an order having satisfied that they fully understand and can comply with all requirements of the intended purchase. In the event of any uncertainty or lack of detail in relation to information provided, they shall duly bring this to the attention of the purchaser.

The supplier shall utilise suitably competent / trained staff in the fulfilment of the requirements.

Cantor + Nissel Supplier Agreement Terms and Conditions

The Supplier shall provide certificates of conformity when providing goods from the following categories:

- Dyes and Inks
- Lens Material
- Crimp tops
- Vials
- Bungs

The supplier shall perform process validations where the resultant output performances are not verified by subsequent Quality Control activities.

The supplier shall perform all works under the control of their ISO 13485 accredited Quality Management System or similar. In the event of a change to scope, or loss of accreditation, the supplier shall without delay notify the purchaser. The supplier shall provide all updated certification to the purchaser for their record holding requirements.

The supplier shall provide to the purchaser any necessary information on the product and/or processes employed so as to allow the purchaser to comply with its obligation as legal manufacturer to hold such details in the associated Medical Device File(s) and/or technical files, and to comply with downstream legislative requirements under REACH regulation (1907/2006), and CLP regulation (1272/2008).

The supplier shall not make any changes to the design or process for products or services under the scope of this agreement without firstly notifying the purchaser for their considerations and obtaining prior written consent.
All proposed changes must undergo risk assessments in relation to the potential impact of the change upon the device safety and performances, and be duly considered by the purchaser in respect of their regulatory responsibilities as legal manufacturer for significant change reportability, and re-approval, in line with any product registration held.

The supplier shall control its environments of manufacture and processing to prevent contamination of any products, including the prevention of cross-contamination with any substances of human or animal origin.

The supplier shall perform quality control activities so as to ensure the scope of supply meets the condition of purchase and shall be supportive to the purchaser in the event timely complaint handling investigations.

Test instrumentation used by the supplier in Quality Control activities shall be periodically calibrated and suitably accurate for its intended purpose. All equipment shall be confirmed to be within calibration at time of use and a record of such equipment use shall be documented in any applicable batch record for traceability purposes.

The supplier shall safeguard products from mix-up, contamination and damage during production and storage.

The supplier shall employ control in any delivery of goods so as to safeguard the supply from damage or contamination occurring in transportation.

The supplier shall ensure deliveries and/or services provided are accompanied by a delivery note or other certification allowing traceability to the supply or services provided.

The supplier shall permit the purchaser to audit the supplier including the supplier’s premises, in relation to scope of products or services provided as part of the purchaser’s supplier approval program when required.

Cantor + Nissel Supplier Agreement Terms and Conditions

The supplier shall also permit the purchasers notified body, or competent authority, as may be applicable, to audit the supplier including the supplier's premises in accordance with regulatory requirements relating to the approval of medical devices placed on the market.

Batch records for items manufactured and/or processing records for services provided, shall be maintained by the supplier for a minimum of 10 years.

The supplier, as may be applicable, shall extend these same controls to any subcontractor they may utilise in their own outsourcing or products or services under this agreement. Copies of such quality and regulatory agreements raised by the supplier with their outsourcing partner shall be made available to the purchaser in order that such information can be made available to regulatory bodies for purpose of process audit requirements that may be applicable.

All documents and records maintained by the supplier in relation to this agreement shall be available in English language.