TERMS RELATING TO QUALITY, REGULATORY, REPORTING AND CONSIGMENT STOCK

Version 3.0 – 1 December 2022

These Terms relating to Quality, Regulatory, Reporting and Consignment Stock ("Quality and Regulatory Terms") apply to the sale by Terumo Europe NV and its affiliates ("TERUMO") of goods and services to the customer ("Buyer") and form an integral part of the Terms and Conditions of Sale of TERUMO.

These Quality and Regulatory Terms may be changed from time to time by TERUMO without notice. The latest version will always be available on TERUMO's website.

Article 1 - Quality requirements

When Buyer purchases the goods for the purpose of supplying them on the market in the course of a commercial activity (including, without limitation, distributing or reselling), the Buyer will:

- ensure a traceability system by maintaining suitable record of the goods reference, lot or serial number, quantity, customer information and installation date (if applicable), during at least 15 years for disposable products, for active equipment and for implantable devices. This traceability system shall include information about the patient for whom the good was used, where applicable;

- store and keep, preferably by electronic means, the UDI of the goods with which Buyer has been supplied or which Buyer has supplied further, at least if those goods belong to Class III implantable devices or any other group defined in further implementing acts to MDR (EU) 2017/745;

- verify that the goods are in conformity with the laws and regulations of the targeted market. For MDR- territory this includes but is not limited to completing the verification according MDR (EU) 2017/745 Article 14 (2);

- store, handle and transport the goods in accordance with the product specifications and with the EU Guideline 2013/C343/01 ("*Guidelines on Good Distribution Practices of Medicinal Products for Human Use*") as may be updated from time to time;

- report to TERUMO any complaint or report communicated by its customers, end-users or service agents about the goods they have made available no later than three (3) business days from being informed. If translation to English is required, five (5) business days is permitted. Buyer must apply all reasonable efforts to obtain and send to TERUMO the relevant good for investigation;

- report to TERUMO within two (2) business days, any complaint or report communicated by its customers, end-users or service agents and/or by local authorities about suspected incidents related to the goods leading to injury or potential injury of a patient or user and related to the use of the goods. Particularly in case of serious public health threat Buyer must report to TERUMO immediately and no later than 48 hours;

- provide necessary support to TERUMO for the implementation of Field Safety Corrective Actions, initiated and instructed by TERUMO or any authorized institution. Buyer will assure that such action is executed for all the goods involved and will inform TERUMO on the progress of the action.

Article 2 - Regulatory requirements

2.1. For the purpose of this clause, the terms "distributor", "placing on the market", "making available on the market", "putting into service", "medical device", "accessory for a medical device" shall have the meaning as defined in Regulation (EU) 2017/745 as amended or replaced from time to time (hereafter "MDR").

2.2. If and to the extent that:

- Buyer qualifies as a distributor; and
- Buyer places on the market, makes available on the market or puts into service a medical device or an accessory for a medical device in the European Union;

Buyer shall comply with the obligations applicable to distributors (where Buyer qualifies as a distributor) or with the obligations applicable to importers (where Buyer qualifies as an importer) under MDR.

2.3. If there is any conflict or inconsistency between a term in the present Quality and Regulatory Terms and a provision in the MDR, the latter provision shall prevail.

Article 3 – Packaging

3.1 Ordered goods will be delivered in their original cardboard package, unless the Parties agree on different packaging. TERUMO reserves the right to modify its goods and packaging without prior notice. Ordered quantities may be modified in order to meet the standard packaging units.

3.2 Buyer accepts that one box (sales unit) may contain multiple goods and only one single copy of the instructions for use. Further copies of such instructions for use will be provided free of charge by TERUMO if requested by Buyer.

3.3 In the event that Buyer intends to include the goods as device constituents in a co-packaged combination product(s), the Buyer shall incorporate the applicable parts (determined by risk based assessment) of the instructions for use, safety and performance information or labeling (where applicable) in the Patient Information Leaflet of the combination product(s).

Article 4 – Consignment stock

4.1. All goods in consignment remain the property of TERUMO until full payment of all invoices, including interest, indemnity and possible taxes.

4.2. Buyer ensures that the goods are used according to the "first expiring – first out" system, in order to prevent expiry.

4.3. Goods returned from consignment stock must be in their original packaging. Any good returned from Buyer which is damaged, soiled, not maintained in the required conditions as indicated by TERUMO or not in useable condition shall be charged to Buyer at the discretion of TERUMO.

4.4. Buyer is responsible for ensuring that all goods are adequately maintained, kept in good working order, and handled only by adequately trained staff.

While the goods are on Buyer's premises, Buyer is responsible for:

(i) maintaining traceability of the goods;

(ii) ensuring the correct storage of the goods, including any storage conditions as specified in the product specifications, and for any deterioration which may take place;

(iii) the use of the goods, including expired goods; and

(iv) advising TERUMO of stock use in a timely manner after consumption, and for generating a purchase order for the items consumed.

4.5 The Buyer will verify the shelf life of any good before use, in order to prevent the use of expired goods on patients.