

SPECIAL TERMS AND CONDITIONS REGARDING TO THE MEDICAL DEVICES AND PERSONAL DATA PROTECTION

Based on

- **MEDICAL DEVICE REGULATION MDR 2007/47/EC, which replaces the Medical Devices Directive (MDD) 93/42/EEC;**
- **REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);**

DISTRIBUTOR Commitments regarding to the medical device

- 1. To collect end-users (health institution – the customer organization the primary purpose of which is the care or treatment of patients or the promotion of public health) contact data and to provide these data to SOFTNETA by request:** During the validity of distributorship agreement DISTRIBUTOR undertakes to collect end-users contact data for the notification purpose in case on PRODUCT (medical device) recall or field safety corrective action. DISTRIBUTOR undertakes to provide collected end-users contact data to SOFTNETA by request (not later than within 8 hours from gathering request), or in cases when he is not able or becomes aware that he will not be able to properly implement the commitments of the DISTRIBUTOR under the distributorship agreement (hereunder) during the maintenance period of the PRODUCT sold (i.e. 1 year from the release date of the PRODUCT. Data should be submitted to SOFTNETA by e-mail support@softneta.com.
- 2. Immediately notify each end-user in case of recall and submit data to SOFTNETA.** Actions in case on medical device (“PRODUCT”) recall¹ (request from a manufacturer to return a product after the discovery of safety issues or product defects that might endanger the consumer or put the maker/seller at risk of legal action): Upon receipt of information on recall from the market, the DISTRIBUTOR should immediately (but not later than within 8 hours from gathering information about recall) notify each end-user to whom PRODUCT was sold. Data about the end-users notification should be submitted to SOFTNETA by e-mail support@softneta.com not later than within 24 hours after notification.
- 3. To notify SOFTNETA in case when DISTRIBUTOR commitments are taken by another legal entity:** DISTRIBUTOR should notify SOFTNETA by e-mail support@softneta.com no later than 3 days before the takeover of this agreement.
- 4. Forward the information about complaints or reports from healthcare professionals, patients or users to the manufacturer.** DISTRIBUTOR that have

¹ “Recall” means any measure aimed at achieving the return of a device that has already been made available to the end user.



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 SOFTNETA and, where applicable, the SOFTNETA'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 representative and the importer informed of such monitoring and provide them with any information upon their request.

5. **Provide information for competent authority by request.** DISTRIBUTOR 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.
6. **Ensure traceability of devices:** DISTRIBUTORS and IMPORTERS shall cooperate with SOFTNETA or authorised representatives to achieve an appropriate level of traceability of devices: Economic operators shall be able to identify the following to the competent authority, for the period at least 10 years: (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.
7. **Identify the target markets and necessary translation of the label and Information for Users:** DISTRIBUTORS must identify the target markets and necessary translation of the label and Information for Users and provide the information for MANUFACTURER.

Cases in which obligations of manufacturer (SOFTNETA) apply to IMPORTERS, DISTRIBUTORS OR OTHER PERSONS

1. A DISTRIBUTOR, IMPORTER or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:
 - (a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a DISTRIBUTOR or IMPORTER enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in Medical Device Regulation;
 - (b) changes the intended purpose of a device already placed on the market or put into service;
 - (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.
2. The 1 subparagraph shall not apply to any person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.
3. The following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
 - (a) provision, including translation, of the information supplied by the manufacturer,



relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

4. A DISTRIBUTOR or IMPORTER that carries out any of the activities mentioned in points (a) and (b) of paragraph 3 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established. DISTRIBUTORS and IMPORTERS shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2.3 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the DISTRIBUTOR or IMPORTER is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the Medical Device Regulation.
5. At least 28 days prior to making the relabelled or repackaged device available on the market, DISTRIBUTORS or IMPORTERS carrying out any of the activities mentioned in points (a) and (b) of paragraph 3 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mockup of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the DISTRIBUTOR or IMPORTER shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 3, attesting that the quality management system of the DISTRIBUTOR or IMPORTER complies with the requirements laid down in paragraph 4.

DISTRIBUTOR Commitments regarding to processing of personal data

Selling item – medical software – is a tool for data handling/managing (including personal data, depending on the end user decision). Necessity and scope of personal data depends only on the end user decision. **Software installation and support services could be implemented remotely. For this purpose end user may create login for SOFTNETA or DISTRIBUTOR. Having login SOFTNETA or DISTRIBUTOR could access personal data**



of end user coworkers and clients (such data may include health data).

Data controller – customer.

Data processor – SOFTNETA or DISTRIBUTOR (as it's mentioned in distributorship agreement part "software install and technical support").

Personal data processing actions: installation and technical support of the software.

Personal data storage location: Customer premises / third parties premises / cloud.

- 1) **Data processing legality:** DISTRIBUTOR ensure that all services, which are subject of distributorship agreement, are implemented according to the General Data Protection Regulation
- 2) **Access to the personal data:** Access to the personal data could be given only to the persons which personally are signed **non-disclosure agreement**.
- 3) **Data processing countries:** In case, if end user gives DISTRIBUTOR a remote access, the Data shall be processed exclusively in the countries, mentioned in a Contract. DISTRIBUTOR shall ensure that the Data are processed (and accessed) exclusively in the specified countries. It may only be accessed from another country following the express written approval of end user.
- 4) **Technical and organizational measures:** DISTRIBUTOR ensure sufficient technical and organizational measures by implementing actions, required for the subject of the distributorship Contract. End user could get acquainted with Technical and organizational measures description by written request.
- 5) **DISTRIBUTOR takes responsibility for Personal data controller (customer) notification** that he (customer) is responsible for the actions regarding to the data breach information for data subjects and controlling authority.
- 6) **Data breach.** In case of data breach DISTRIBUTOR should immediately (but not later than during 24 hours) communicate with the SOFTNETA Data Protection Officer (contacts of Data Protection Officer are public available www.softneta.com)

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SOFTNETA Commitments regarding to processing of personal data

- 1) SOFTNETA ensure that all services, which are subject of the contract, are implemented according to the General Data Protection Regulation.
- 2) Access to the personal data could be given only to the persons which personally are signed non-disclosure agreement.
- 3) SOFTNETA ensure sufficient technical and organizational measures by implementing actions, required for the subject of the Contract. End user could get acquainted with Technical and organizational measures description by written request.

