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

Based on

- **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);**
- **DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.**

DISTRIBUTOR Commitment 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 this 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 this agreement (hereunder) during the maintenance period of the PRODUCT sold (i.e. 2 years from the release date of the PRODUCT. Data should be submitted to SOFTNETA by e-mail support@softneta.com.

2) If the DISTRIBUTOR do not provide end-users data to SOFTNETA by request, DISTRIBUTOR takes responsibility for actions in case on medical device recall or field safety corrective action (Recall is any measure aimed at achieving the return of a device that has already been made available to the end user. Field safety corrective action means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market): 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 about recall 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.

DISTRIBUTOR Commitment 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 (legal entity who has purchased medical software).

Data processor – SOFTNETA or DISTRIBUTOR (as it's mentioned in section of this agreement "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 this contract, 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:** The Software will be installed on personal data storage location. DISTRIBUTOR does not have direct access to Data. In case, if end user gives DISTRIBUTOR a remote access / direct access from personal data storage location, 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. If countries are not mentioned in the Contract, by default is treated that the Data could be processed (and accessed) only in EU countries.

4) **Technical and organizational measures:** DISTRIBUTOR 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.

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 each DISTRIBUTOR should immediately (but not later than during 24 hours) communicate with SOFTNETA Data Protection Officer using below mentioned contact:
SOFTNETA Data Protection Officer (contacts of Data Protection Officer are public available www.softneta.com).

Name, Surname: Raimundas Mikalauskas

Tel. +370 630 06808

e-mail: dpo@softneta.com

SOFTNETA Commitment regarding to processing of personal data

1) SOFTNETA ensure that all services, which are subject of this 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.