COMMITMENT OF APPLIMED'S DISTRIBUTORS

Applimed SA (Applimed) delivers its products and provides its services in Switzerland and abroad. Applimed manufactures and sells single-use medical devices and procedure packs. For further information, visit the website: www.applimed.ch. By becoming Applimed's distributor, the present document applies as per communicated and agreed General Terms and Conditions of Sale.

1. SCOPE OF THE DOCUMENT

The purpose of this document is to define the responsibilities of Applimed and of its distributors regarding the legal and quality requirements in regards to the MDR 2017/745 and the Medical Device Ordinance RS 812.213 (versions in force). Distributors are active in the sales of medical devices as defined in Article 14 of MDR 2017/745. This document applies to all medical devices supplied by Applimed which are then distributed (Products).

2. QUALITY MANAGEMENT SYSTEM

Applimed commits to maintain a Quality Management System ("QMS") that meets the requirements applicable to the Product(s). The distributors commit to maintain the necessary procedures that meet the requirements applicable to the distribution of the Product(s). In particular, the distributors must comply with the regulatory requirements listed below.

3. TRACEABILITY

The distributors must co-operate with Applimed in order to achieve an appropriate level of traceability of devices. In particular, they commit to keep a record, for a period of at least 10 years from the date on which the device was acquired or delivered, of:

- Any economic operator to whom they have directly supplied a device;
- Any health institution or healthcare professional to which they have directly supplied a device.

This record must at the very least include the reference number (REF) as well as the batch (LOT) number of the devices supplied to the parties mentioned above. The distributors must transmit all of the records mentioned above to Applimed, in the event of termination or change of activity. These requirements apply to any distributors to whom Applimed's own distributors supply the Products. The distributors must ensure that their own distributors(s) respect these obligations.

4. STORAGE AND SHIPPING

The distributors must issue and maintain procedures to control the warehouse(s) and storage location(s) in order to prevent mixing, deterioration, contamination and other adverse effects.

Distributors must ensure that, while the Products are under their responsibility, the storage and transport conditions comply with the conditions set by the manufacturer of the Products, in order to prevent damage, deterioration or changes in the characteristics of the Products. The distributors must make sure that the Products are stored in order to ensure stock rotation and that they are managed using FIFO ("First In, First Out") methodology.

5. VERIFICATION OF THE DEVICES

When making a device available on the market, the distributors must, in the context of their activities, act with due care in relation to the requirements applicable. Before making a device available on the market, distributors must verify that:

a. The device bears the conformity marking (i.e. CE mark);
b. The declaration of conformity has been drawn up;
c. The device is accompanied by the product information;
d. For devices that have been imported, that the registered trade name or registered trade mark, registered place of business and the address of the importer at which they can be contacted can be found on the device or on its packaging or in a document accompanying the device;
e. The manufacturer has assigned a UDI when and where applicable.

The distributors may apply a sampling method in order to verify these points, with the exception of point d.

The distributors must not make the device available to the market if they have a reason to believe that a device is not in conformity with the applicable requirements, until it has been brought into conformity. The distributors must inform Applimed, and, where applicable, its authorised representative and the importer of the non-conformity.

If the distributors consider or has reason to believe that the device presents a serious risk or is a falsified device, it must also inform the competent authority of the state in which it is established.

6. VIGILANCE AND COMMUNICATION

If the distributors have a reason to believe that a device is not in conformity with the applicable requirements after placing the device on the market, the distributors must immediately inform Applimed, and, where applicable, the manufacturer's authorised representative and importer of the non-conformity. If the distributors consider or has a reason to believe that the device presents a serious risk and Applimed is not respondent, the distributors must also immediately inform the competent authorities of the states in which it made the device available, giving details, in particular, of the non-conformity and of any corrective action taken.

The distributors must co-operate with Applimed, and, where applicable, the manufacturer's authorised representative, 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.

In case of reporting, the distributors undertake:

- To not issue Incident Reports, Field Safety Notice (FSN) and Field Safety Corrective Actions (FSCA) / recalls of devices without proper prior instruction to do so by Applimed. However, if the distributors consider or has reason to believe that the device presents a serious risk and Applimed is not respondent, the distributor must immediately inform the competent authorities of the states in which it made the device available, and if applicable the notified body that issued the certificate for the Product, giving details, in particular, of the non-conformity and of any corrective action taken.
- To strictly follow the instructions of Applimed in a timely manner and with systematic confirmations to Applimed.
- To consider that Applimed will be responsible for the control and follow-up of these actions. However, obligations under Article 14 MDR for distributors prevail in case Applimed does not or is unable to honor its obligations under Article 10 MDR.

In case of Field Safety Correction Action (Recall or Withdrawal), the distributors undertake:

- To co-operate with Applimed to ensure that any necessary corrective action to bring a device into conformity, to withdraw or to recall it, as appropriate, is taken.
- When requested to do so, to carry out recall activities on behalf of Applimed and to inform the manufacturer of the status at times agreed in the recall set-up.
- To store recalled devices in quarantine until instructions are received from Applimed.
- To keep a register of withdrawals and recalls and to keep Applimed informed of such progression monitoring and provide them with any information upon their request.

Applimed undertakes:

- To inform the distributors about any safety, performance or any compliance issue regarding the medical devices that could lead to a serious incident immediately after being made aware.
- To confirm in writing receipt of any devices-related complaints forwarded by the distributors.
- In case the distributors express the suspicion in writing that the circumstances of the customer complaint / information received by the distributors could lead to a reportable incident, to confirm in writing that he will investigate and keep the distributors promptly informed about the results of the investigation.
- To investigate the complaints reported to Applimed by the distributors and to respond to the distributors in a timely manner.
- To keep the distributors informed about recalls (or any other FSCA) of devices initiated by Applimed.

7. COMPLAINT HANDLING

The distributors must keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep Applimed, the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

If the distributors have received complaints or reports from other economic operators, healthcare professionals, patients or users about suspected incidents related to a device they have made available, the distributors must immediately forward this information to Applimed,

the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer.

8. REQUESTS FROM COMPETENT AUTHORITIES

The distributors must, 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. The manufacturer or their authorised representative may provide this information directly to the competent authorities, in which case the distributors are considered to have fulfilled their obligations.

The distributors must 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. The distributors, upon request by a competent authority, must provide free samples of the device.

9. CHANGES TO INFORMATION AND PRODUCT

Commercial documentation, as well as supporting documents, such as the IFU provided by the manufacturer, labelling, denomination of the device, and technical data cannot be changed or modified by the distributors. Applimed cannot be held responsible otherwise for any change in the content of the documents and labelling.

The distributors must not make any changes to the products, whether it is on the device itself or on its packaging or labelling.

The intended uses of the Products may not in any case be changed.

The distributors assume the obligations incumbent on manufacturers fully in the case that the distributors make any of the abovementioned changes without prior authorisation from Applimed, according to Article 16 of the MDR 2017/745.

10. DISTRIBUTORS VERSUS GOVERNMENT AND INDUSTRY REGULATIONS

Distributors shall be thoroughly familiar with applicable government regulations concerning the use, handling, sale and disposition of the Products. Distributors shall possess all required governmental permits and licenses and approvals required to distribute the Products. Distributors shall comply with all laws, ordinances and regulations applicable to its business and to the sales, demonstration, use and disposition of Products and agrees to indemnify and hold Applimed harmless from all costs and liabilities arising out of any failure of distributors to comply therewith.

11. AUDITS

The distributors undertake to accept audits from Applimed's Notified Body (NB) (at the NB's request) in the context of activities, processes and products covered by the present distribution agreement.

12. TRANSLATIONS / LANGUAGES USED IN LABELLING

The distributors acknowledge that Instructions for Use (IFUs) and labels contain information about the safe use of the product, including warnings, cautions, and contraindications where appropriate and required. The distributors shall ensure that the aforementioned documents comply with the language requirements of each country where the products are sold, in accordance with the MDR (Language requirements for manufacturers) (latest version available).

13. REGULATORY REGISTRATIONS

Compliance with the MDR 2017/745 requirements and any other applicable national legal requirements and registration requirements in the Territory of distribution (meaning countries or regions in which the distributors engage in making available medical devices) shall be ensured by Applimed and the distributors jointly according to their legal responsibilities. The distributors are expected to communicate to Applimed whether specific requirements apply to the devices distributed depending on the country of distribution (such as National registration, languages requirements, etc). Applimed will be responsible for providing products that, as a minimum, have received regulatory approval for marketing from the European Community (CE Marking).