Authorised Representative Agreement

We, TEKNIMED SAS located at 11-12 rue d'Apollo, ZA Montredon, 31240 l'Union FRANCE, as a supplier of medical products

and

Pharmony S.R.L., located at 4, Durlesti Str., Durlesti town, Chisinau, MD2071, Republic of Moldova (hereinafter referred to as Company B)

Have agreed as follows, regarding the safe handling of the medical devices (hereinafter referred to as "Products") manufactured and supplied by **Company A** to **Company B** in order to comply with the requirements of Government Decision no. 418 of June 5, 2014, concerning Medical Devices (GDMD) and the "Guidelines on a Medical Devices Vigilance System."

APPOINTMENT

Company A hereby appoints Company B upon the terms and conditions herein contained to be the official representative for the products manufactured by Company A.

And whereas Company B expresses their desire to enter into an agreement with Company A upon the terms and conditions set forth in this Agreement.

RESPONSIBILITIES OF BOTH PARTIES - GENERAL INFORMATION

Company B is authorized to perform registration, renewal, and variation of the registration of the medical devices mentioned in this agreement to the Competent Authorities.
Company A shall provide to Company B for the registration of medical devices the following information:

a) Declaration of conformity,
b) Copy of the label, packaging, and instructions for use,
c) Notified Body certificates,
d) Post-market surveillance process and data,
e) Relevant clinical data/notification,
f) Details of any distributors/suppliers putting Republic of Moldova-marked devices on the market,
g) Incident reports and reports on corrective actions taken.

Company B shall be responsible for registration, monitoring, and communication of all claims from customers and the market related to the products of Company A and to notify Company A upon receiving such claims.

Incident Reporting

Company B shall maintain an updated Quality System and communicate the vigilance procedures to Company A for coordination and continuity of Company A's own Quality System. Company B shall communicate any other procedures upon the request of Company A. Company B shall work closely with Company A and shall transmit without delay any information coming from the Agency. In case of a special request by the Agency, particularly in relation to incident reporting, Company B will agree with Company A on the position statement and answers to give to the Agency. In case of differences in positions between Company A and Company B, the position of Company A will prevail and will be supplied to the Agency with a format endorsement of Company A. Company B shall have a qualified person to be in contact with the Agency.

In case of incidents known first by Company A, Company B will be immediately informed and will immediately perform with Company A the analysis of the accident. Company B will write and send to the concerned Agency the initial report including Company A's actions if available, such as sample analysis, analysis of historic lot records, and potential corrective actions to be taken in the further manipulation of the product like withdrawal, recall from the market.

Company B shall notify the Agency about the following timelines apply in a case of:

a) Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the Company A of this threat.
b) Death or UNANTICIPATED serious deterioration in the state of health: IMMEDIATELY (without any delay that could not be justified) after the Company A established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.
c) Others: IMMEDIATELY (without any delay that could not be justified) after the Company A established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potential reportable INCIDENT there is still uncertainty about whether the event is reportable, Company A must submit a report within the timeframe required for the type of INCIDENT.

As soon as information and incidents assessment from Company A are available, Company B writes and sends the final incidents report. In any case, Company B submits these reports to Company A for preliminary approval. Company B will keep these records available for the Agency.

According to the stipulation of medical equipment plant GDMD, Company A must summarize the experience of manufacturing products, take proper measures, and have the right to know the incident occasionally happened, and take proper measures.

a) The mishandling of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to the death of patients and users and deterioration of health condition.
b) The above-mentioned, the technical property of the products or the problems in medicine, the company has the right to recall the products of the same lot and specification.

Field Safety Notice
If Company A finds that there is a problem of quality of the products on the market, it should immediately issue a Field Safety Notice for the users, so they could be able to take the necessary measures (including the recall of the products).

Recall
In case the products are withdrawn from the market, Company A should recall the products immediately. Before recalling the products, Company B should inform the Agency.

Return of Products to the Company
Company A shall send advisory notice to Company B in this region and order him to cease selling the products. Recall the products sold to the market or inform the users, ask the Company B in this region to inform the local governing department where the products are sold. After Company B recalls the products, Company A should agree with Company B on the mode of transportation or time and return the products to the company for disposal.

Traceability of Sold Products
Company A shall keep records of serial numbers, batch numbers for all products delivered to Company B.
Company B shall keep records of the Products delivered to the users or distributors. In this case, the traceability of sold products can be performed at any time upon request. Records shall include the following information:
Name and address of the customer,
Quantity dispatched,
Date transferred to the customer,
Serial or production lot numbers.

It is agreed that these records should be available for inspection upon request by Company A or by the relevant authorities.

Technical Documentation
Company A shall establish necessary procedures to prepare and maintain Technical Documentation, including the Declaration of Conformity, for the products manufactured by

Company A to be able to comply with the GDMD requirements. Company A shall transfer the agreed Technical documentation and Declaration of Conformity to Company B.

Company B shall keep to keep a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate (including any amendments and supplements of such a certificate), issued in accordance with Article 56 MDR or Article 51 IVDR at the disposal of competent authorities for the period referred to in Article 10(8) MDR and Article 10(7) IVDR, of the devices for which it is designated. This includes a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market.

Company A The shall ensure that the Company B has the necessary documentation 'permanently available' in order to fulfil the tasks specified in Article 11(3) of the Regulations, is outlined in the third sub-paragraph of Article 10(8) MDR and Article 10(7) IVDR. 'Permanently available' in this context means it will be mandatory for the manufacturer to provide the authorised representatives with the requisite documentation, in their most recent versions and for certificates this includes amendments or supplements, either in hard or electronic copy.

Instruction Manual
Company A shall be responsible for the content of the instruction manual (user's guide) and shall ensure the availability of the English version of the instruction manual for Company B.

Company B shall ensure the required instruction manuals to be provided to the customer in the official language of the Republic of Moldova.

Person Responsible for Regulatory Compliance (PRRC) at Authorized Representative:

Balan Olivian
Position: Biomedical engineer
Email: **olivian.balan@pharmony.md**

Company B reserves the right to designate another person as PRRC at any time, with prior notification to the competent authorities and the manufacturer.

Termination of the mandate
The Company B has the right to terminate the mandate if the manufacturer acts contrary to its obligations under the Regulations.
The Company A must adhere to its obligations under the Regulations to avoid the termination of the mandate by the authorized representative.

For the following Product Categories:

- *Surgical cement with Gentamicin*

Company A: *Carole LEONARD* , *Signature*

Président

Teknimed
11-12 rue d'Apollo - Z.I. Montredon
31240 L'Union - FRANCE
Tél. (33) 5 34 25 10 60

Company B: **Alexandru ȘARCO,** *Chisinau*

Director