Agreement

Name: Guangzhou Wondfo Biotech Co., Ltd.

Address: Guangzhou Wondfo Biotech Co., Ltd., legal address: No. 8 Lizhishan Road, Science City, Huangpu District, Guangdong, P.R. China, hereinafter referred to as Company A,

(hereinafter referred as company A)

And

Name: ProfiLabDiagnostic SRL

Address: 6, str. Dokuceaev, of.61, Chisinau, mun. Chisinau, the Republic of Moldova

(hereinafter referred as company B)

Have agreed as follow, regarding the safe handling of the medical devices (hereinafter called "Products") manufactured and supplied by Company A to Company B in order to comply with the requirements of the Government Decision **no.418 of 05 June 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 official representative for the products manufactured by Company A.

And whereas Company B expresses their desire to 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, variation of the registration.

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 (in all languages requested by the countries where the device is marketed),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data,
e) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
h) Incident reports and reports on corrective actions taken.

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

Incident Reporting

Company B shall maintain an update 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 of other procedures upon request of the Company A.

Company B shall work closely with Company A and shall transmit without delay any information coming from the Agency. In case of special request by the Agency, particularly in relation with incidents reporting, the Company B will agree with Company A on the position statement and answers to give to the Agency.

In case of difference 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 the Company A.

Company B shall have a qualified person to be in contact with the Agency.

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

Company B shall notify Agency about the following time lines 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 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 with 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, the 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 mangle of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to 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

The Company A finds that there is a problem of quality of the products on the market, it should immediately give out 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 of products are withdrawn from the market, the Company A should recall the products immediately. Before recalling the products, the Company B should inform the Agency.

Return the 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 the Company B recalls the products, Company A should agree with the 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 the Technical Documents including the Declaration of Conformity available to the Agency for at least five years after the last products has been sold.

Company A shall provide to Company B and additional documentation if required by Agency.

Instruction Manual

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

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

The agreement is viable for the following products and product categories:

1. Wound Dressings (Zinc Oxide Tape, Non-woven Tape, PE Tape, Silk Cloth Tape, Waterproof Adhesive Tape, Non-woven Wound Dressing Tape, PE Wound Dressing Tape, Medical Surgical Tape, Wound Plaster, First Aid Plaster, Corn Plaster, etc.)
2. Dental and Surgical Equipment (Medical Face Mask, Dental Bib, Mob Cap, Surgical Gown, Absorbent Underpad, Shoe Cover, Sterile Surgical Gloves, Stomatology sets, Dental Rolls, etc.)
3. Laboratory Equipment (Petri Dish, Microscope Slide, etc.)
4. Other Examination Equipment (Isolation Gown, Cervical Spoon, Wooden Tongue Depressor, Cyto Brush, etc.)
5. Other Medical Disposable Devices (Vaginal Speculum, Urine Bag, Colostomy Bag, Alcohol Pad, Adult Diaper, Urine Container, Stool Container, Foley Catheter, Endotracheal Catheter, etc.)

Company A:	*Zhang Yue* *Director*	*18.02.2025* *Guangzhou, China*	*Signature*
Company B:	*Irina Varman* *Director*	*18.02.2025* *Chisinau, Moldova*	*Signature*

			Ambalaj
OCG-102	**Coagulometru OCG -102**	Analizator	1
Cod catalog	**Parametri**	**Proba**	**Ambalaj**
W480	**PT/INR**	Capillary Blood/ Citrated Venouswhole bood 20ul Shelf Life: 18 months	24T/set
W481	**APTT**	Capillary Blood/ Citrated Venouswhole bood 20ul Shelf Life: 18 months	24T/set
W482	**FIB**	Capillary Blood/ Citrated Venouswhole bood 20ul Shelf Life: 18 months	24T/set
W483	**ACT**	Capillary Blood/ Citrated Venouswhole bood 20ul Shelf Life: 18 months	24T/set
W484	**TT**	Capillary Blood/ Citrated Venouswhole bood 20ul Shelf Life: 18 months	24T/set
	Control	Termen de valabilitate: 12 luni	2 Flacoane/set