Agreement on Safe Handling of Medical Devices

SAN-O-SUB MBB srl
with registered office at
v.le Leonardo da Vinci 168, Trezzano S/N (MI) Italy
hereinafter referred to as Company A,

and

Labromed Laborator SRL
with registered office at
str. Trandafirilor 15, of. 134, Chisinau, Moldova MD 2038,
hereinafter referred to as Company B,

have the following agreement on safe handling of medical devices (hereinafter called “Products”), manufactured and supplied by Company A to Company B, in order to comply with the requirements of Government Decision on Medical Devices (GDMD) (no. 702, 703, 704 July 11, 2018) and the governmental “Guidelines on a Medical Devices Vigilance System”.

APPOINTMENT

Company A hereby appoints Company B on the terms and conditions of the present agreement as its authorized representative responsible for products obtained from Company A for the Republic of Moldova.

RESPONSIBILITIES OF THE PARTIES

Company B is authorized to register Products of Company A as well as to renew and to update the registration, when necessary and with an approval of Company A. For registration of medical devices, Company A shall provide to company B with the following documentation and 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 undertaken by the Medicines and Medical Devices Agency, Republic of Moldova (henceforth referred to as Agency),

f) Relevant clinical data/notifications,

g) Details of any distributors/suppliers that supply the same devices on the market of the Republic of Moldova,

h) Incident reports and reports on corrective actions taken.

Company B shall be responsible for filing and monitoring customer complains related to the Products distributed by it in the republic of Moldova and communicating these complaints to Company A.

Incident Reporting

Company B shall maintain an up-to-date Quality System and communicate vigilance procedures to Company A for coordination and maintenance of Company A's own Quality System. Company B shall communicate any other procedures upon 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 with incident 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 formal 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 Company A, Company B will be immediately informed and will immediately perform the analysis of the accident with Company A. Company B will write the initial report and send it to the concern of the Agency, the report including a description of Company A's actions, such as sample analysis, analysis of historic lot record, and potential corrective actions to be taken in further manipulations of the product, like a withdraw or a recall from the market.

Company B shall notify the Agency about an incident in accordance with the following time lines:

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 of patient's state of health: IMMEDIATELY (without any delay that could not be justified) after 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 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 the relevant information and incident assessment from Company A are provided, Company B writes and sends to the Agency the final incident 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.

Company A shall inform Company B of any modifications to the medical devices registered by company B in the Republic of Moldova as well as changes in labels and user instructions.

Field safety notice

If Company A becomes aware of a problem with quality of their product released on the market, it should immediately send a Field Safety Notice to Company B, so that Company B could take necessary steps (including a recall of the product).

Recall

If a product is to be withdrawn from the market, Company A should recall the product immediately. Before recalling the product, Company B should inform the Agency.

Return of the product to company A

Company A shall send an advisory notice to Company B with requests (i) to stop selling the product in their region of distribution, (ii) to recall the products already sold on the market, (iii) to make product users aware of the issue, and (iv) to inform the local governmental department of places where the products are sold.

After Company B recalls the products, Company A should agree with the Company B on the mode of and time of transportation and return the products to company A for disposal.

Traceability of Sold Products

Company A shall keep records of serial numbers and batch numbers for all products delivered to Company B.

Company B shall keep records of the Products delivered to the users or distributors to ensure that the traceability of sold products can be performed at any time upon request. Traceability 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 will be available for inspection upon request by Company A or by 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 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 additional documentation, if required by the 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 instructions 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.

Company A SAN-O-SUB MBB srl	*Name and Position:* *Caterina Brivio* *Quality manager*	*place, date:* Trezzano S/N (Milan) 24/04/2025	*Signature:* SAN – O – SUB MBB srl Via Leonardo da Vinci, 168 20090 TREZZANO SUL NAVIGLIO (MI) C.F./P.IVA: 12321560968
Company B	*Name and Position:* Alexandr Ermicev, director	*place, date:* str. Trandafirilor 15, of. 134, Chisinau, Moldova MD 2038	*Signature:*

Digitally signed by Ermicev Alexandr
Date: 2025.04.29 13:00:05 EEST
Reason: MoldSign Signature
Location: Moldova
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