Agreement

To whom it may concern,
between

Manufacturer: Suzhou Manwell Medical Equipment Co., Ltd (address: Room B707-A, Tower B, Huijin Business Centre, Yangshe Town, Zhangjagang City, Jiangsu Province, China.)

and authorized representative:

I.M BECOR SRL (address: Calea Orheiului 111/5, Chisinău, Republic of Moldova.)

Have agreed as follow, regarding the safe handling of the medical devices (hereinafter called "Products") manufactured and supplied by Suzhou Manwell Medical Equipment Co, Ltd. to **IM "BECOR" SRL** for the territory of the Republic of Moldova in order to comply with the requirements of the local Government Decision no.702/2018, 703/2018 and 704/2018 concerning Medical Devices and the "Guidelines on a Medical Devices Vigilance System".

RESPONSIBILITIES OF BOTH PARTIES

I.M. BECOR S.R.L. is the authorized representative for the Republic of Moldova and shall perform registration and renewal of the registration in the state Register of Medical Devices.

Suzhou Manwell Medical Equipment Co., Ltd shall provide to **I.M. BECOR S.R.L.** 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 for placing the Product on the market),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data, related to the Products, to the extent reasonably necessary for registration and vigilance obligations in the Republic of Moldova,
e) Technical documentation reasonably necessary and relevant to a specific market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers appointed by the Manufacturer for placing the Products on the market in the Republic of Moldova to the extent known by the Manufacturer,
h) Incident reports and reports on corrective actions taken related to the Products.

I.M.BECOR S.R.L shall be responsible for registration, monitoring the Moldovan market and for collecting and promptly forwarding to **Suzhou Manwell Medical Equipment Co., Ltd** all customer complaints, claims and market feedback related to the Products, and for notifying the Agency in accordance with the applicable vigilance requirements and as coordinated with **Suzhou Manwell Medical Equipment Co., Ltd.**

Incident Reporting

I.M. BECOR SRL shall maintain an up to date Quality System and shall communicate the applicable vigilance procedures to **Suzhou Manwell Medical Equipment Co., Ltd.** for coordination and continuity to own Quality System.

I.M. BECOR SRL shall work closely with **Suzhou Manwell Medical Equipment Co., Ltd.** and shall send without delay any information received from the Medicines and Medical Devices Agency.

In case of incidents known first by the **Suzhou Manwell Medical Equipment Co., Ltd,** the **I.M. BECOR SRL** will be immediately informed and will immediately perform with the Company named above the analysis of the accident. **I.M. BECOR S.R.L.** will draft the initial report and submit it to the **Suzhou Manwell Medical Equipment Co., Ltd** for preliminary approval prior to submission to the Agency unless mandatory legal timelines require earlier submission in such case **Suzhou Manwell Medical Equipment Co., Ltd** shall be informed in advance to the extent practicable.

I.M.BECOR SRL 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 of this threat to **Suzhou Manwell Medical Equipment Co., Ltd.**

b) Others: IMMEDIATELY (without any delay that could not be justified) after **Suzhou Manwell Medical Equipment Co., Ltd** has 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.

As soon as information and incidents assessment from **Suzhou Manwell Medical Equipment Co., Ltd** are available, **I.M.BECOR SRL** writes and sends the final incidents report. In any case, **I.M.BECOR SRL** submits these reports to **Suzhou Manwell Medical Equipment Co., Ltd** for preliminary approval. **I.M.BECOR SRL** will keep these records available for the **Medicines and Medical Devices Agency.**

Recall

In case of products are withdrawn from the market or a field safety actions is required ,the **Suzhou Manwell Medical Equipment Co., Ltd** shall decide and implement the appropriate corrective actions, including withdrawal/recall, based on a documented risk assessment and in coordination with IM Becor SRL and where required the Agency without undue delay where necessary. Before a withdrawal/recall is initiated in the Republic of Moldova, the **IM BECOR SRL** shall inform **the Medicines and Medical Devices Agency** as required by applicable law and in coordination with **Suzhou Manwell Medical Equipment Co., Ltd** .

Traceability of Sold Products

Suzhou Manwell Medical Equipment Co., Ltd shall keep records of batch numbers and, where applicable, serial numbers for all products delivered to **IM BECOR SRL.**

IM BECOR SRL shall keep records of the Products delivered to the users. 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, batch numbers

It is agreed that these records should be available for inspection upon request by **Suzhou Manwell Medical Equipment Co., Ltd** or by the relevant authorities.

Technical Documentation

Suzhou Manwell Medical Equipment Co., Ltd shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity and shall send the agreed Technical documentation and Declaration of Conformity to **IM BECOR SRL**.

IM BECOR SRL shall keep the Technical Documents including the Declarations of Conformity available to the Agency for at least five years after the last products have been placed on the market in the Republic of Moldova or longer if required by applicable law.

Suzhou Manwell Medical Equipment Co., Ltd, shall provide to **I.M. BECOR S.R.L** any additional documentation reasonably necessary and relevant to specific request by the Agency in connection with the Products and the Republic of Moldova.

Instruction Manual

Suzhou Manwell Medical Equipment Co., Ltd, 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 **IM BECOR SRL**.

IM BECOR SRL shall ensure the required instruction manuals to be provided to the customer in official language of the Republic of Moldova.

Signed for and on behalf of **Suzhou Manwell Medical Equipment Co., Ltd**	Signed for and on behalf of **I.M BECOR SRL**
By:	By:
Name: Frank Lu	Name: Iurie Bezer
Title: General Manager	Title: Director IM BECOR SRL

苏州迈威医疗设备有限公司
Suzhou Manwell Medical Equipment Co.,Ltd

Digitally signed by Lazari Cristina
Date: 2026.03.27 16:26:38 EET
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