

**MEMORANDUM OF COOPERATION  
BETWEEN  
THE MINISTRY OF HEALTH, LABOUR AND WELFARE  
OF JAPAN  
AND  
THE MEDICAL DEVICE AUTHORITY  
OF MALAYSIA  
ON  
MEDICAL DEVICE REGULATORY COOPERATION FRAMEWORK**

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Medical Device Authority of Malaysia (Malaysia MDA), (hereinafter referred to collectively as “the Participants” and individually as a “Participant”),

INTENDING to promote mutual beneficial regulatory cooperation in the area of medical device in accordance with the applicable laws and regulations of the respective countries.

HAVE REACHED the following recognition:

**1. Purpose**

1. The purpose of this Memorandum of Cooperation (hereinafter referred to as “this MOC”) is to establish and facilitate a constructive regulatory cooperation in the areas of medical device.
2. This MOC is not intended to create any legally binding obligations between the Participants under national or international law.

**2 . Areas of Cooperation**

1. The Participants will promote the exchange of information and regulatory cooperation in the areas of medical device and the relevant administrative and regulatory matters within the jurisdiction of the Participants.
2. The Participants will also encourage to conduct regulatory cooperation in the fields of:
  - a. Scientific collaboration;
  - b. Personnel trainings; and
  - c. Cooperation in multilateral fora.

3. Any other areas of regulatory cooperation mutually decided upon subsequently by the Participants in writing.

### **3. Means of Cooperation**

1. The Participants will hold meetings, as necessary, to discuss major topics related to the areas of regulatory cooperation.
2. The meetings will be held in Japan or in Malaysia in-person basis, or other mechanisms including virtual way as mutually decided upon by the Participants.
3. English will be used as a common language for the meetings.

### **4. Working Group**

1. A Working group (hereinafter referred to as “the WG”) will be established at the meeting based on the Participants’ mutual interests.
2. The WG may consider the holding of related meetings, symposia and training workshops in association with the meeting, based on the Participants’ mutual decisions.
3. The Participants may jointly decide to invite representatives from the relevant industries and academia to participate in the WG, depending on the agenda of the meeting.

### **5. Minutes**

The minutes of the meetings will be drawn up in English by the Participants after each meeting.

### **6. Contact Points**

The Participants will designate the following respective contact points for the implementation of this MOC:

- a. For MHLW: Director, Office of International Regulatory Affairs
- b. For Malaysia MDA: Director, International and Industry Relations Division

## **7. Financial Matters**

1. Each Participant will bear its own costs in relation to the implementation of the cooperative activities under this MOC.
2. When deemed necessary and by mutual consent, the Participants may invite funds from any third party to support the activities under this MOC.

## **8. Resolution of Differences**

Any differences arising from the interpretation and/or implementation of this MOC will be resolved amicably through consultations between the Participants including through diplomatic channels.

## **9. Confidentiality of Information**

1. The Participants will use the information and documents exchanged between them only within the scope of the decided purposes; and each Participant will not disclose any exchanged information to a third party without the written consent of the Participant which is the source of it.
2. The Participants confirm that this clause will survive notwithstanding the discontinuation of this MOC.

## **10. Protection of Intellectual Property Rights**

1. The Intellectual property rights will be protected in conformity in accordance with the respective national laws, rules and regulations of the Participants and with the international agreements to which the two countries are party.
2. The use of the name, logo and/or official emblem of any of the Participant on any publication, document and/or paper is prohibited without prior written approval of that Participant.

## **11. Commencement, Modification and Discontinuation**

1. The cooperation under this MOC will commence on the date of its signature and will continue for a period of five (5) years.
2. This MOC will be automatically renewed for another successive period of five (5) years, unless a written notice is given by either Participant of its intention

to discontinue this MOC to the other Participant at least ninety (90) days before the intended date of discontinuation.

3. This MOC may be modified with the mutual written consent of the Participants and such modifications will be an integral part of this MOC.
4. The discontinuation of this MOC will not affect the duration or implementation of on-going cooperation, project or other activities which have been confirmed upon before the date of the discontinuation of this MOC, unless the Participants decide otherwise.

SIGNED in duplicate in Tokyo on Jun 8, 2026 in Japanese, and English languages, both texts having equal value. In case of any divergence of interpretation of the texts, the English text will prevail.

For  
The Ministry of Health, Labour and  
Welfare of Japan,

For  
The Medical Device Authority of  
Malaysia,

**MIYAMOTO NAOKI**  
Director General  
Pharmaceutical Safety Bureau  
Ministry of Health, Labour and Welfare

**Ts. Dr. MURALITHARAN PARAMASUA**  
Chief Executive  
Medical Device Authority