

**MEMORANDUM OF UNDERSTANDING**  
**BETWEEN**  
**THE CZECH OFFICE FOR STANDARDS, METROLOGY AND TESTING**  
**OF THE CZECH REPUBLIC**  
**AND**  
**THE MEDICAL DEVICE AUTHORITY OF MALAYSIA**  
**ON COOPERATION IN THE FIELD OF MEDICAL DEVICE**

This Memorandum of Understanding (hereinafter referred to as "MoU") is signed on 20<sup>th</sup> November 2023 between the Czech Office for Standards, Metrology and Testing (hereinafter referred to as "ÚNMZ") and the Medical Device Authority of Malaysia (hereinafter referred to as "MDA") (hereinafter referred to singularly as "the Participant" and collectively as "the Participants").

In recognizing that

- A. ÚNMZ is a state budgetary organization performing the state administration in the fields of technical standardization, metrology, state testing, and tasks in the area of technical regulations and standards under the Ministry of Industry and Trade of the Czech Republic, established under Act No 20/1993 Coll., on Ensuring of Exercise of the State Administration in the Field of the Technical Standardization, Metrology and Testing, and having its address registered office at Biskupský dvůr 1148/5, 110 00 Prague 1, Czech Republic.
- B. MDA is the National Regulatory Authority to regulate the medical device and its industries under the Medical Device Act 2012 [Act 737] and having its address at Level 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, 63000 Cyberjaya, Selangor.
- C. The Participants, without the intention to create a legally binding document, express their desire to cooperate within the framework of this MoU for the purpose of strengthening, promoting and developing cooperation between both Participants in the field of medical devices and any other related and relevant matters in accordance with the legal framework of their respective States, and in a manner that serves their mutual interests.

**Paragraph 1**  
**Areas of Cooperation**

The Participants have hereby express desire to cooperate and share continuously information in medical devices field to their concerns such as:

1. exchange of information on legislative and regulatory acts in the field of medical devices;
2. exchange of information on possible programs and projects of medical devices development;
3. exchange of experience on international and regional experts' committees' medical devices activities;
4. exchange of experience on application of information technologies and any other tools in the field of medical devices;
5. consultations in the field of placing on the market of medical devices;
6. organizing joint meetings or seminars for both Participants and stakeholders;
7. organizing specialist's study visit with a view to examining international experience in the area of medical devices; and
8. any other areas of cooperation to be mutually agreed upon by the Participants.

**Paragraph 2**  
**Forms of Cooperation**

The mutual cooperation between the Participants may be undertaken through the following means:

1. organizing of bilateral meetings either physically and/or virtually to discuss topics related to scope of cooperation and/or any other areas of cooperation arrangement;
2. organizing of seminars focused on strengthening capacity and share experiences and information related to medical devices.

**Paragraph 3**  
**Financial Arrangements**

The Participants declare their willingness to bear, in compliance with relevant national laws and legislation, their own costs for the realization cooperation under this MoU and all activities held in connection with this MoU are subject to budgetary availability of the Participants.

#### **Paragraph 4**

##### **Participation of Third Party**

Either Participant may invite the involvement of a third party in the joint projects and/or programs being carried out in framework of cooperation under this MoU when consensus from both Participants is obtained.

#### **Paragraph 5**

##### **Confidentiality**

The Participants, in accordance with their national legislation, share the understanding that information about the results of the cooperation within the framework of this Memorandum are confidential and intended solely for their internal use.

#### **Paragraph 6**

##### **Revision, Modification and Amendment**

If the Participants intend to revise, modify, or amend this Memorandum, it may be done by mutual consensual written communication.

#### **Paragraph 7**

##### **Suspension**

The Participants share the understanding that they may temporarily suspend, either in whole or in part, cooperation under this MoU.


#### **Paragraph 8**

##### **Beginning and Termination of Cooperation**

The activities according to this MoU may commence after its signature. In case of intention to terminate cooperation according to this MoU, Participants declare their willingness to inform each other in writing about this in advance.

SIGNED at Prague on the 20<sup>th</sup> of November 2023 in two (2) original counterparts in English, one for each Participant.

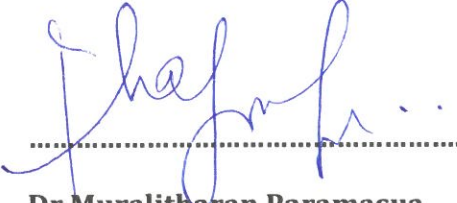
Signed by )  
for and on behalf of )  
Czech Office for Standards, Metrology )  
and Testing )  
in the presence of: )  
 )  
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**Mr Viktor Pokorný**  
**President**

Signed by )  
for and on behalf of )  
Medical Device Authority )  
in the presence of: )  
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**Dr Muralitharan Paramasua**  
**Chief Executive**