MEMORANDUM OF COOPERATION
BETWEEN THE JAPAN-TAIWAN EXCHANGE ASSOCIATION AND
THE TAIWAN-JAPAN RELATIONS ASSOCIATION
ON THE FIELD OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM REQUIREMENTS

THE JAPAN-TAIWAN EXCHANGE ASSOCIATION and THE TAIWAN-JAPAN RELATIONS ASSOCIATION (hereinafter individually referred to as the "Side" or collectively as the "Sides"), having regard to paragraph 3 (7) of the Arrangement between the Interchange Association (now the Japan-Taiwan Exchange Association) and the Association of East Asian Relations (now the Taiwan-Japan Relations Association) for the Establishment of the Respective Overseas Offices on 26 December 1972, and under the Arrangement between the Interchange Association (now the Japan-Taiwan Exchange Association) and the Association of East Asian Relations (now the Taiwan-Japan Relations Association) for the Establishment of the Framework of the Cooperation on the Medical Products Regulation on 5 November 2013, will cooperate with each other in order to obtain necessary consent from the relevant authorities of both Sides with regard to the matters as described below.

1. Both Sides will cooperate for medical device Quality Management System (QMS) audit reports and the QMS compliance certifications to be utilized to reduce the burden of both Japanese and Taiwanese manufacturers in demonstrating compliance of medical devices, including In Vitro Diagnostics (IVDs) ,with the QMS regulations by relevant authorities of each Side.

   For this purpose, the Japan-Taiwan Exchange Association will request the relevant authorities of Japan, namely the Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), to:

   accept medical device QMS audit reports and the QMS compliance certifications, which are prepared by the Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) in Chinese and translated by manufacturers into English or Japanese; and

   regard the medical device QMS audit reports and the QMS compliance certifications as part of the information to demonstrate the manufacturer's compliance with Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostics (MHLW Ministerial Ordinance No. 169); and

   put Taiwanese manufacturers into the same risk level with that of United

States and European Union, and make the most of the QMS audit reports and the QMS compliance certifications to reduce on-site inspection according to the notification (PFSB/CND (Yakushoku-kanma) Notification No. 1024-10 October 24, 2014) attachment 1, 2(1)c)[For “mutual usages of Inspection results of other Inspection bodies, etc.”, they will be as follows: For foreign manufacturing sites in partner countries etc. with which Japan has exchanged an MOU etc., when a copy of a certificate of suitability or a QMS Inspection result report issued by the partner country etc. based on prescriptions of the MOU etc. has been submitted, or other certain requirements have been satisfied].

For the same purpose, the Taiwan-Japan Relations Association will request the relevant authorities of Taiwan, namely TFDA, to:

accept medical device QMS audit reports and the QMS compliance certifications, which are prepared by PMDA or MHLW’s Registered Certification Bodies (RCBs) in Japanese and translated by manufacturers into English or Chinese; and

regard the medical device QMS audit reports and the QMS compliance certifications as part of the information to demonstrate the manufacturer’s compliance with Taiwan medical device GMP regulation (Chapter 2, Part 3 Good Manufacturing Practices for Medical Devices of Pharmaceutical Good Manufacturing Practice Regulations); and

require none of the quality system procedural documentation except quality manual of Japanese manufacturers for medical device QMS document inspection, except for some procedures of quality system when necessary; and announce the list of RCBs and approve any new RCB seeking to participate in the exchange of medical device QMS audit reports and the QMS compliance certifications nominated by MHLW except for when necessary.

2. Both Sides will cooperate for prior notification of relevant authorities’ visit schedule to medical device manufacturers in Japan/Taiwan in order to facilitate mutual understanding of respective quality management system regulations.

3. Both Sides will cooperate to hold training workshops on the occasion of annual meetings to enhance the understanding of medical device QMS requirements in Japan and Taiwan and request the relevant authorities for their support.

4. This Memorandum will enter into force on the date of signature.

5. This Memorandum may be modified by mutual written consent of the Sides.

6. This Memorandum may be terminated by either Side by giving the other Side a 90-day prior written notice.

In witness whereof, the representative of the Japan-Taiwan Exchange Association and the representative of the Taiwan-Japan Relations Association signed this Memorandum.

Signed in Taipei on 30 November 2018 in duplicate in English.

FOR THE JAPAN-TAIWAN EXCHANGE ASSOCIATION:	FOR THE TAIWN-JAPAN RELATIONS ASSOCIATION:
_____	_____
Chairman	Chairman