TERMS OF REFERENCE
OF THE ASEAN MEDICAL DEVICE COMMITTEE
FOR THE ASEAN AGREEMENT ON MEDICAL DEVICE DIRECTIVE

Article 1: Background

The ASEAN Consultative Committee for Standards and Quality was formed by the ASEAN Economic Ministers in 1992 with the aim of removing technical barriers to trades in order to facilitate the implementation of the Common Effective Preferential Tariff (CEPT) Agreement and to realize the ASEAN Free Trade Area (AFTA).

The 24th ACCSQ Meeting held from 3-4 August 2004 proposed the establishment of the Medical Device Product Working Group (MDPWG) to implement the specific measures for the integration of the medical device sector under the Roadmap for Priority Integration Sectors for the Healthcare Sector. The ACCSQ's proposal was approved by the SEOM I/36 held on 17-19 January 2005 in Yogyakarta, Indonesia.

Through intensive discussion the MDPWG further developed an ASEAN Medical Device Directive to enhance cooperation amongst Member States in ensuring the safety, quality and claimed benefits of all medical device products marketed in ASEAN and to eliminate restrictions to trade of medical device products amongst Member States through harmonization of technical requirements, as well as adoption of the ASEAN Medical Device Directive (AMDD).

The AMDD was finalized at the MDPWG HOD Meeting held in October 2013 in Singapore and by the ACCSQ in December 2013 and subsequently by SEOM 1/45 Meeting in January 2014. Upon the signing of the AMDD by the 46th ASEAN Economic Ministers Meeting through ad-referendum basis, the ASEAN Medical Device Committee is established, in accordance with Article 14 "Institutional Arrangements" of the AMDD to oversee the implementation of the Directive.

Article 2: Objective and Scope of the AMDC

2.1 Coordinate, monitor and evaluate and the implementation of the ASEAN Medical Device Directive;

2.2 Consider, discuss and endorse issues on revision of Annexes of AMDD, with reference to any update of international guidelines available, i.e GHTF/IMDRF. Provide a forum for discussion of issues, including sharing of experience concerning the transposition of AMDD into national legislation as well as implementation of the AMDD;

2.3 Consider measures to enhance the operation of the AMDD;

2.4 The AMDC may establish an ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing the technical and safety issues.

2.5 Discuss and formulate technical assistance needed for the implementation of AMDD, in particular to narrow development gap among ASEAN Member States.

Article 3: Structure of the AMDC

The AMDC will be composed of:

3.1 The Chair and Vice- Chair. Both Chair and Vice- Chair shall not represent the same ASEAN Member States;

3.2 At least two representatives from each Member States' Regulatory Authority responsible for Medical Devices. The representative may be accompanied by their delegation at meetings of the AMDC;

3.3 The representative(s) from the ASEAN Secretariat;

3.4 Any Representative of ACCSQ may participate at AMDC Meetings as observers.

The AMDC may also invite the following during AMDC Meeting:

3.5 Any Resource persons and experts approved by the Heads of Delegations to provide technical inputs on particular issue during AMDC meetings;

3.6 Any Dialogue Partners as approved by the Heads of Delegations to update AMDC on particular Agenda on technical assistance for AMDC activities;

3.7 The representatives from the ASEAN Medical Device Industry Association may be invited to meetings of the AMDC on specific Agenda Item and may be consulted on matters concerning the Medical Device Industry;

The AMDC may arrange a Public Private Forum in accordance to the Rules of Procedure for Private Sector Engagement (PPE) under ASEAN Economic Community, endorsed by 23rd AEM Retreat on 9 March 2017, Passay City, Philippines. The Public Private Forum may be arranged following the conclusion of any AMDC Meeting. Arrangement of the Public Private Forum will follow the PPE Rules of Procedures appears as **ANNEX 1.**

Article 4: Terms of Office

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The tenure for the AMDC chairmanship shall be for a period of one year and followed by alphabetical order. In the event an AMS cannot take up the position of Chair or Vice-Chair, the next AMS by alphabetical order will be offered the position

Article 5: The Duties and Responsibility of the Chair and Vice- Chair

5.1 The Chair of the AMDC shall preside at every meeting of the AMDC and ensure that all interests are heard, keep discussion to the point, judge when a consensus of opinion has been reached and express it by a summing up progress in order that the minutes are clear and precise.

5.2 Prior to any discussion, the Chair shall consult with the members of the AMDC on the subject to be covered during discussion.

5.3 The Vice- Chair shall assist the Chair in implementing the above duties and responsibilities and shall assume these duties and responsibilities when the Chair is not available.

Article 6: Procedures

6.1 The AMDC shall provide a forum and mechanism to discuss issues, sharing information and reaching decisions associated with the operation of the ASEAN Medical Device Directive.

Article 7: Meeting and Reports

7.1 The AMDC shall meet at least once a year;

7.2 All meetings of the AMDC shall be convened by the Chair and the Vice-Chair.

7.3 AMDC will report to the ASEAN Consultative Committee on Standanrds and Quality (ACCSQ);

7.4 Notice of the meeting will be sent to AMDC members at least 30 days before the date of the meeting. The agenda and supporting documents will be sent to members at least 15 working days before the date of the meeting.

7.5 Every decision of the AMDC shall be reached by consensus of the members. Any disagreement amongst the AMDC shall be settled in accordance with Article 20 of the AMDD.

(Chair, ASEAN Medical Device Committee)

(Vice-Chair, ASEAN Medical Device Committee)