Recognized foreign regulatory authorities and notified bodies and the respective approval types eligible for conformity assessment by way of verification process

01 TGA, Australia

TGA license

Health Canada 02

Health Canada medical device license

NANDO database of EU 03

- EC Certification (CE Marking) against EU MDD, EU IVDD and EU AIMDD, as below:

For **general** medical device:

- Annex II Section 3 or Annex V of MDD (for Class IIA)
- Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB)
- Annex II Section 3 and 4 of MDD (for Class III)
- Annex II Section 3 and 4 of AIMDD (for active implantable medical device)

For **IVD** medical device:

- Annex IV (Including Section 4 and 6) of IVDD (for List A IVD)
- Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-testing IVD)
- Annex III, EC declaration of conformity (Section 1 to 5 of Annex III). Applicable for only Class B IVD medical device in accordance with Medical Device Regulations 2012;

or

- EC Certification (CE Marking) against EU Medical Device Regulations and EU IVD Regulations; *or*
- Listed in European Database on Medical Devices (EUDAMED)

04 MHLW, Japan

- Pre Market Certification from a Japanese Registered Certification Body (RCB and PMDA).
- Pre Market Approval from MHLW

USFDA 05

- US FDA 510(k) clearance letter
- US FDA pre-market approval (PMA) letter

06 UK, MHRA

For Great Britain and Northern Ireland

- Public Access Database for Medical Device Registration; or
- UKCA Certification; or
- EC (CE Marking) and UKNI Certification

Reference: https://portal.mda.gov.my/index.php/documents/surat-pekeliling-pbpp-mda-s-circular-letter/2053-surat-pekeliling-pbpp-bil-2-2014-eng-revision-5/file

Prepared on 6th Feb 2024

Medical Device Authority Malaysia