Overview of Medical Device Registration Framework

Based on medical device definition in Section 2 of Act 737

- ✓ Specify medical device intended purpose
- ✓ Rule & Grouping
- ✓ Compile technical document CSDT

Local Manufacturer

Authorised Representative

MeDDAS 21+ MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

14-60 working days upon submission of complete documents

Regulatory Oversight & Enforcement

Public Search Medical Device Authority Register (MDAR)

Conduct conformity assessment procedure with registered CABs **exclude Class A*

Apply for medical device registration

Evaluation by MDA

Issuance of certificate

Register for 5 years

Place safe MD on the market

Class	Application Fee
A	100
B	250
C	500
D	750

Class	Registration Fee
A	-
B	1000
C	2000
D	3000
Combination	5000

Re-registration

Change Notification

VERIFICATION

FULL CONFORMITY ASSESSMENT

MHRA Regulating Medicines and Medical Devices

MHLW Ministry of Health, Labour and Welfare of Japan

FDA U.S. FOOD & DRUG ADMINISTRATION

European Union

Australian Government Department of Health

Health Canada

Prepared on 6th Feb 2024

Medical Device AUTHORITY MALAYSIA