



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

14-60 working days upon submission of complete documents



Regulatory Oversight & Enforcement



Place safe MD on the market

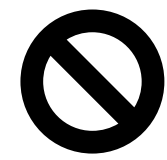
Class	Application Fee
A	100
B	250
C	500
D	750

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



VERIFICATION

FULL CONFORMITY ASSESSMENT



Prepared on 6th Feb 2024

