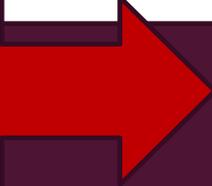


**ORDER IS  
UNDER  
WAY**



**NEW POLICY:  
EXEMPTION OF  
CONFORMITY ASSESSMENT BODY**

- 1. RE-REGISTRATION OF MEDICAL DEVICE
- 2. MEDICAL DEVICES NOVEL TECHNOLOGY
- 3. MEDICAL GAS SYSTEM

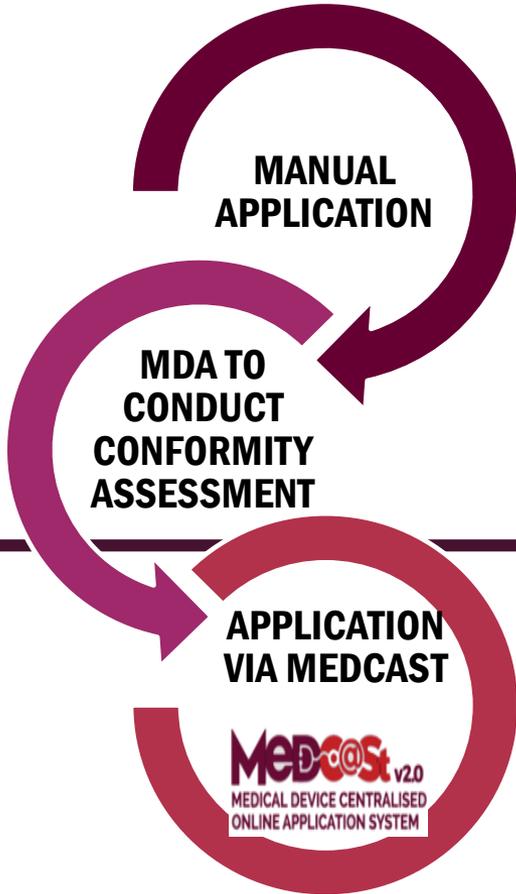


**CONFORMITY  
ASSESSMENT WILL BE  
DONE BY MDA**



**REGISTER**

# 1. RE-REGISTRATION OF MEDICAL DEVICE



MEDICAL DEVICE CLASSIFICATION	CONFORMITY ASSESSMENT FEES
Class A	-
Class B	800
Class C	800
Class D	800



## 2.NOVEL MEDICAL DEVICE REGISTRATION

MEDICAL DEVICE CLASSIFICATION	FULL ASSESSMENT
CLASS A	-
CLASS B	RM1,200 / MAN-DAY PRE-EVALUATION RM500 / APPLICATION
CLASS C	RM1,200 / MAN-DAY PRE-EVALUATION RM500 / APPLICATION
CLASS D	RM1,200 / MAN-DAY PRE-EVALUATION RM500 / APPLICATION



**ON-SITE AUDIT  
&  
CHARGES**



**APPLICATION FEE & REGISTRATION FEE**



**REGISTRATION**

# 3. MEDICAL GAS SYSTEM REGISTRATION

MEDICAL DEVICE CLASSIFICATION	VERIFICATION	FULL ASSESSMENT
CLASS A	-	-
CLASS B	RM800	RM1,200 / MAN-DAY PRE-EVALUATION RM500 / APPLICATION
CLASS C	RM800	RM1,200 / MAN-DAY PRE-EVALUATION RM500 / APPLICATION
CLASS D	RM800	RM1,200 / MAN-DAY PRE-EVALUATION RM500/ APPLICATION



# ORDERS

- (1) Medical Device (Exemption) Order 2015 – P.U. (A) 135
  - Exemption from requirement Section 5
- (2) Medical Device (Exemption) Order 2016 – P.U.(A) 103
  - Exemption from registrations of medical devices
  - Exemption from establishment license
  - Exemption from conformity assessment for Class A medical device
- (3) Medical Device (Declaration) Order 2017 – P.U.(A) 339
  - Declaration Non- Corrective Contact Lense as medical device