

## **Medical Devices**

### Medical Devices Registration

PRODUCT REGISTRATION AND EVALUATION FEES FOR MEDICAL DEVICES	Revised Fees (effective 1 July 2024)
Class B	
(i) Application fee	\$560
(ii) Immediate route fee	\$1,000
(iii) Abridged route fee	\$2,010
(iv) Full route fee	\$3,900
(v) Full route (Priority Review Scheme* Route 1)	\$4,420
(vi) Full route (Priority Review Scheme* Route 2)	\$5,660
Class C	
(i) Application fee	\$560
(ii) Immediate route fee	\$3,340
(iii) Expedited route fee	\$3,340
(iv) Abridged route fee	\$3,900
(v) Full route fee	\$6,250
(vi) Full route (Priority Review Scheme* Route 1)	\$7,000
(vii) Full route (Priority Review Scheme* Route 2)	\$9,000
Class D	
(i) Application fee	\$560
(ii) Expedited route fee	\$5,930
(iii) Abridged route fee	\$6,250
(iv) Full route fee	\$12,000
(v) Full route (Priority Review Scheme* Route 1)	\$13,600
(vi) Full route (Priority Review Scheme* Route 2)	\$17,500
Class D with a registrable drug	
(i) Application fee	\$560
(ii) Abridged route fee	\$10,600
(iii) Full route fee	\$75,600

\*Refer to <u>Priority Review Scheme</u> page for more details



# List of Revised Fees for Health Products

Revised fees are applicable to applications submitted on and after 1 July 2024

ANNUAL RETENTION FEES FOR MEDICAL DEVICES LISTED ON SINGAPORE MEDICAL DEVICE REGISTER (SMDR)	Revised Fees (effective 1 July 2024)
Class B	\$39
Class C	\$67
Class D	\$134
Class D with a registrable drug	\$134

CHANGE OF REGISTRANT	Revised Fees (effective 1 July 2024)
Application fee for change of registrant	\$880

### **Dealer's Licences for Medical Devices**

DEALER'S LICENCE APPLICATION AND AMENDMENT	Revised Fees (effective 1 July 2024)
New application for or annual renewal of dealer's licence	
Manufacturer	\$1,110
Importer	\$1,110
Wholesaler	\$1,110
Amendment application for dealer's licence	
Manufacturer	\$168
Importer	\$168
Wholesaler	\$168

## **Change Notification**

CHANGE NOTIFICATION	Revised Fees (effective 1 July 2024)
Class B	
Administrative Changes	\$560
Review Changes	\$560
Class C	
Administrative Changes	\$560
Technical Changes	\$1,890
Class D (including devices with a registrable drug)	



# List of Revised Fees for Health Products

Revised fees are applicable to applications submitted on and after 1 July 2024

Administrative Changes	\$560
Technical Changes	\$3,120

#### Free Sale Certificates

FREE SALE CERTIFICATES	Revised Fees (effective 1 July 2024)
Application fee	\$57#
Processing fees:	
for one device and one country	\$57#
for each additional device	\$57#
for each additional country	\$57#

#### **Special Access Route**

SPECIAL ACCESS ROUTES	Revised Fees (effective 1 July 2024)
Unregistered devices requested by qualified practitioners	\$168
Unregistered devices requested by a licensed PHMC	\$390
Import for re-export of unregistered devices	\$280
Unregistered devices for non-clinical purpose	\$280

#### **Pre-Market Consultation**

PRE-MARKET CONSULTATION	Revised Fees (effective 1 July 2024)
Medical device development consultation	\$530 <sup>#</sup> for each device per consultation, for up to two hours
Medical device pre-submission consultation	\$210 <sup>#</sup> for each device application per consultation, for up to one hour

#Goods and Services Tax (GST) is only applicable to health product fees for non-mandatory applications and services. Fees shown are inclusive of GST. HSA will continue to absorb the 1% GST increases which took effect in Singapore from 1 Jan 2023 and 1 Jan 2024, until further notice.