

 A Singapore Government Agency Website [How to identify](#) 

# Registration overview of medical devices

Understand the evaluation routes, fees and turn-around-times applicable when you register your medical device.

## Evaluation routes

Each device registration is done via a specific evaluation route. The evaluation route for your device depends on:

- Risk classification of your device
- Number of prior approvals given by our overseas reference regulatory agencies
- Duration of safe marketing history for your device

The evaluation route of your device will determine the turn-around-time (TAT), fees and documents required for registration.

### Check your device's evaluation route

Answer a few questions to find out the requirements for your device's registration route and whether you need to apply for a license.

[CHECK DEVICE'S ROUTE](#)

## Class A registration

Class A medical devices are exempted from product registration. However, you will need to submit a [product notification application](#) in SHARE for Class A medical devices that you manufacture or import.

## Class B, C and D registration

### ⊖ Registration requirements

# Registration requirements

## Registration requirements

Refer to the table below for an overview of the evaluation routes for Class B, C and D medical devices.

A medical device without prior approval from any of our overseas reference regulatory agencies must undergo a full evaluation.

Evaluation routes	Conditions
Full  Full (Priority Review Scheme)	No prior approval by any of our overseas reference regulatory agencies
Abridged	Approval from at least one of our overseas reference regulatory agencies
Expedited routes: <ul style="list-style-type: none"> <li>● Class C registration (ECR)</li> <li>● Class D registration (EDR)</li> </ul>	ECR-1: <ul style="list-style-type: none"> <li>● Approval from at least one of our overseas reference regulatory agencies</li> <li>● Marketed for at least three years in the respective agencies' jurisdictions</li> <li>● No safety issues globally</li> <li>● No prior rejection/withdrawal by us or any overseas reference regulatory agencies</li> </ul> ECR-2/EDR: <ul style="list-style-type: none"> <li>● Approval from at least two of our overseas reference regulatory agencies</li> <li>● No prior rejection/withdrawal by us or any overseas reference regulatory agencies</li> </ul>

Evaluation routes	Conditions
Immediate Class B Registration (IBR)	<p>Condition 1:</p> <ul style="list-style-type: none"><li>● Approval from at least one of our overseas reference regulatory agencies</li><li>● Marketed for at least three years in the respective agencies' jurisdictions</li><li>● No safety issues globally</li><li>● No prior rejection/withdrawal by us or any overseas reference regulatory agencies</li></ul> <p>Condition 2:</p> <ul style="list-style-type: none"><li>● Approval from at least two of our overseas reference regulatory agencies</li><li>● No safety issues globally</li><li>● No prior rejection/withdrawal by us or any overseas reference regulatory agencies</li></ul>

Evaluation routes	Conditions
<p>Immediate routes, solely for standalone medical mobile applications:</p> <ul style="list-style-type: none"> <li>● Class B</li> <li>● Class C</li> </ul>	<ul style="list-style-type: none"> <li>● Approval from at least one of our overseas reference regulatory agencies</li> <li>● No safety issues globally</li> <li>● No prior rejection/withdrawal by us or any overseas reference regulatory agencies</li> </ul>

## ⊖ Devices not qualified for expedited routes

# Devices not qualified for expedited routes

## Class C devices

The following medical devices cannot take the expedited Class C (ECR) route. These devices can only be registered via the full or abridged routes.

- Hip, knee and shoulder joint replacement non-bioactive implants (e.g. non-bioactive metal/polymer implants)

## Class D devices

The following medical devices cannot take the expedited Class D (EDR) route. These devices can only be registered via the full or abridged routes.

- Active implantable devices (e.g. pacemakers, neurostimulators)
- Implantable devices in direct contact with the central circulatory system or central nervous system
- Hip, knee and shoulder joint replacement (e.g. bioactive implants)
- Devices with a registrable drug in a secondary role
- IVD assays (excluding IVD analysers) intended for HIV testing (screening and diagnosis) and blood/tissue donor compatibility testing

## ⊖ Overseas reference regulatory agencies

# Overseas reference regulatory agencies

The approvals that qualify for the abridged, expedited and immediate evaluation routes are listed in the following table. These approvals must be on the same medical device labelled use that is intended for the Singapore market.

Overseas reference regulatory agencies	Recognised approvals
Australia Therapeutic Goods Administration (TGA)	<ul style="list-style-type: none"><li data-bbox="852 191 1333 226">● Device Registration Licence</li></ul>

**Overseas reference regulatory agencies****Recognised approvals**

European Union Notified Bodies (EU NB)

**For Class B**

Via EC certificates issued according to:

- Directive 93/42/EEC Annex II section 3 or Annex V for Class IIa devices
- Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III or MDR Annex XI PART A for Class IIa
- Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs
- In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III for Class B IVD

**For Class C and D**

Via EC certificates issued according to:

- Directive 93/42/EEC Annex II section 3 or Annex III with Annex V for Class IIb
- Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for implantables, or MDR Annex X coupled with Annex XI PART A for Class IIb
- Directive 93/42/EEC Annex II section 3 and 4 for Class III
- Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III,

Overseas reference regulatory agencies	Recognised approvals
	<p>including assessment of the technical documentation for Class III</p> <ul style="list-style-type: none"> <li>● Directive 90/385/EEC Annex II section 3 and 4 for Active Implantable Medical Devices (note: Directive 90/385/EEC is incorporated into MDR and active <u>implantable medical device</u> is Class III under MDR)</li> <li>● Directive 98/79/EC Annex IV including sections 4 and 6 for List A IVDs</li> <li>● IVDR Annex IX Chapter I and Chapter III, including assessment of technical documentation for Class D IVD</li> <li>● Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs</li> <li>● <u>In Vitro Diagnostic Medical Device Regulation (IVDR)</u> Annex IX Chapter I and Chapter III, including assessment of technical documentation for companion diagnostics, self-testing &amp; near-patient testing devices, or IVDR Annex X coupled with Annex XI (except section 5) for Class C IVD</li> </ul>
Health Canada (HC)	<ul style="list-style-type: none"> <li>● Device Registration Licence</li> </ul>

Overseas reference regulatory agencies	Recognised approvals
Japan Ministry of Health, Labour and Welfare (MHLW)	<ul style="list-style-type: none"> <li>● Pre-market certification (Ninsho) from a Japanese registered certification body</li> <li>● Pre-market approval (Shonin) from MHLW</li> </ul>
US Food and Drug Administration (US FDA)	<ul style="list-style-type: none"> <li>● 510K clearance</li> <li>● De Novo</li> <li>● Premarket approval (PMA)</li> </ul>

**NOTE:** Class B, C and D medical devices that are classified and approved/cleared as Class I or Class II exempt in the above reference agencies do not qualify for the abridged, expedited or immediate routes based on these respective approvals.

## Priority Review Scheme

The [Priority Review Scheme](#) provides the option for you to gain faster device registration and market entry for medical devices that are submitted to us through the full evaluation route.

## Fees and turn-around-time

During the evaluation process, we will verify the information and supporting documents you submit, and will contact you if we need additional information from you via an Input Request (IR). Your device registration may be delayed if we do not receive all the necessary information in time.

Refer to [medical device fees and turn-around-time](#) for more information.

## Prepare for registration

You can proceed to our registration guides once you have determined your product's risk classification and evaluation route.

[SEE REGISTRATION GUIDES](#)

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