

BEFORE YOU APPLY

Application to Import and/or Register High-Risk Health Technology

in accordance with the [Bermuda Health Council \(High Risk Health Technology\) Regulations 2024](#)



GETTING READY

Before starting your application, please ensure you have the information and supporting documentation needed for each piece of High-Risk Health Technology (HRHT). Preparing these items in advance will help avoid delays in processing your application.



INFORMATION YOU'LL NEED

Business Information

- Health Service Provider (HSP) (business) name
- Active HSP Licence Number
- Type of application (import, registration, re-registration, disposal or replacement)

Technology Information

- Equipment name and manufacturer
- Model and serial number
- Year of manufacture
- Intended clinical use and target patient population
- Equipment location (fixed or mobile)

Service Delivery

- Days and hours of operation
- Minimum and maximum daily patient capacity
- Current demand and wait times
- Number of personnel operating the equipment
- Training and continuing education information

Equipment Lifecycle

- Purchase date
- Installation date
- Commissioning date
- Date first placed into operation
- Manufacturer's end-of-life/end-of-support date

Maintenance and Inspection

- Maintenance provider
- Inspection provider
- Last and next maintenance dates
- Last and next inspection dates
- Major repairs or component failures (past three years)
- Clinical or operational limitations (if any)

Financial Information

- Initial purchase cost
- Installation/construction costs
- Estimated annual operating costs (e.g. maintenance, software, staffing, utilities, service contracts and other operating expenses)



REQUIRED SUPPORTING DOCUMENTATION

Please have the following documentation available to submit with your application where applicable:

- ✓ Regulatory approval documentation (e.g. FDA, CE, MHRA or another recognised regulatory authority).
- ✓ Manufacturer's specification documentation (radiation-emitting equipment only).
- ✓ Maintenance schedules, service records and/or inspection reports (radiation-emitting equipment only).
- ✓ Floor plan or building drawing showing the location of the equipment (radiation-emitting equipment only).
- ✓ For radiation-emitting equipment, any additional documentation requested by the Health Council, such as shielding or facility drawings, where applicable.



ADDITIONAL DOCUMENTATION THAT MAY BE REQUESTED

During the assessment of your application, the Bermuda Health Council may request further information or documentation to assist in determining your application.



Additional technical specifications or manufacturer information.



Acceptance testing, commissioning, or quality assurance records.



Maintenance history or evidence of repairs.



Clinical, operational or utilisation information.



Any other documents relevant to the assessment of the technology.



DECLARATION

The application must be completed by the owner or an authorised representative of the owner. An authorised representative is someone who has the authority to provide information and make declarations on behalf of the legal entity applying for registration. They must attest that the information provided is true and accurate and provide their name, email address, and electronic signature.