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Health Products and Food Branch Inspectorate

L'Inspectorat de la Direction générale des produits de santé et des aliments



MEDICAL DEVICE EXPORT CERTIFICATES

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Export Certificates

Two types:

- Manufacturer's Certificate to Cover Exports of Medical Devices
- Export Certificate For Medical Devices



Manufacturer's Certificate to Cover Exports of Medical Devices

- a.k.a. certificate of free sale
- device must be manufactured in Canada
- device must be licensed for sale in Canada, or a compliant class 1 device
- certificate issued by the Inspectorate regional offices

Manufacturer's Certificate to Cover Exports of Medical Devices



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Export Certificate for Medical Devices Section 37 of the Act

- device must be manufactured in Canada
- device is not licensed for sale in Canada and/or does not comply with Canadian regulations
- packaging is marked for “export”
- certificate completed and retained by exporter



Export Certificate for Medical Devices Section 37 of the Act



Microsoft Word
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