GUIDANCE DOCUMENTS

Four guidance documents are available to support the interpretation of the new or updated post-market provisions in the Medical Devices Regulations that were published in Canada Gazette Part II on December 23, 2020.

Given that these documents may be updated as new information becomes available, links to the documents on the web have been provided below.

1. Incident reporting for medical devices
2. Foreign risk notification for medical devices
3. Summary reports and issue-related analyses of safety and effectiveness for medical devices
4. Guide to new authorities on the amendments to include power to require assessments and power to require tests and studies