



**Health Santé  
Canada Canada**

# **MEDICAL DEVICE LICENSING REQUIREMENTS**

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## **Life Sciences British Columbia NRC-Industry Research Assistance Program**

### **Health Canada Regulations on Medical Devices**

**Vancouver, B.C.  
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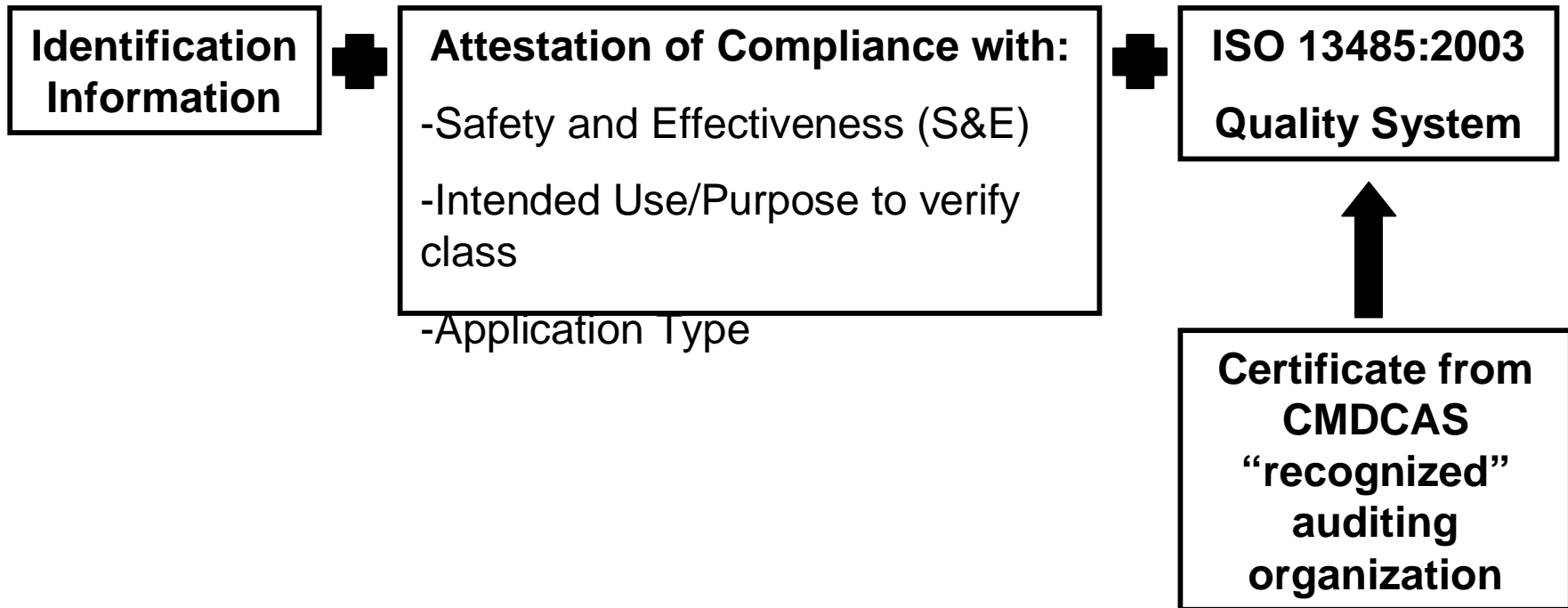
**Health Santé  
Canada Canada**

**Health Products and Food Branch  
Direction générale des produits de santé et des aliments**

# DEVICE LICENCE CLASS II

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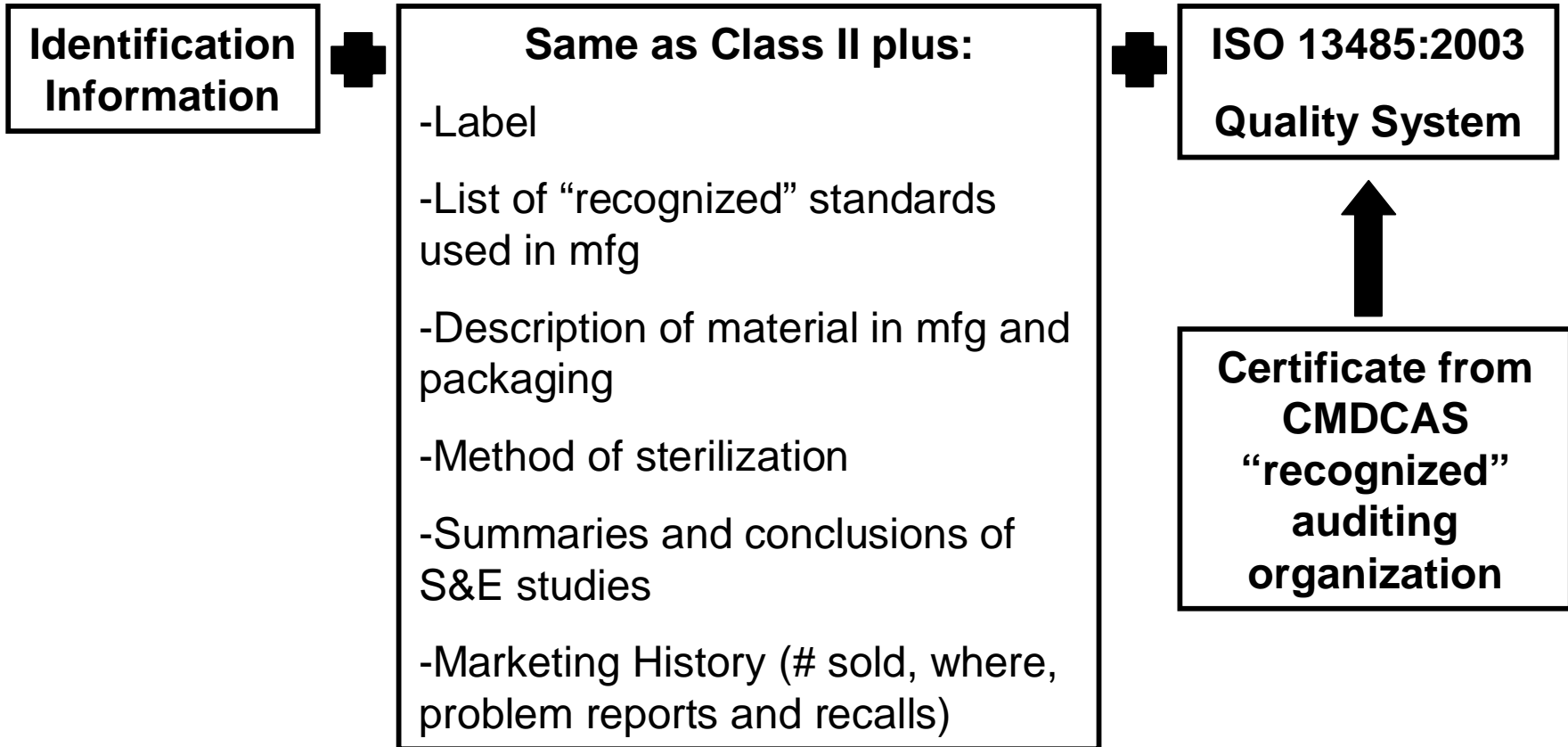
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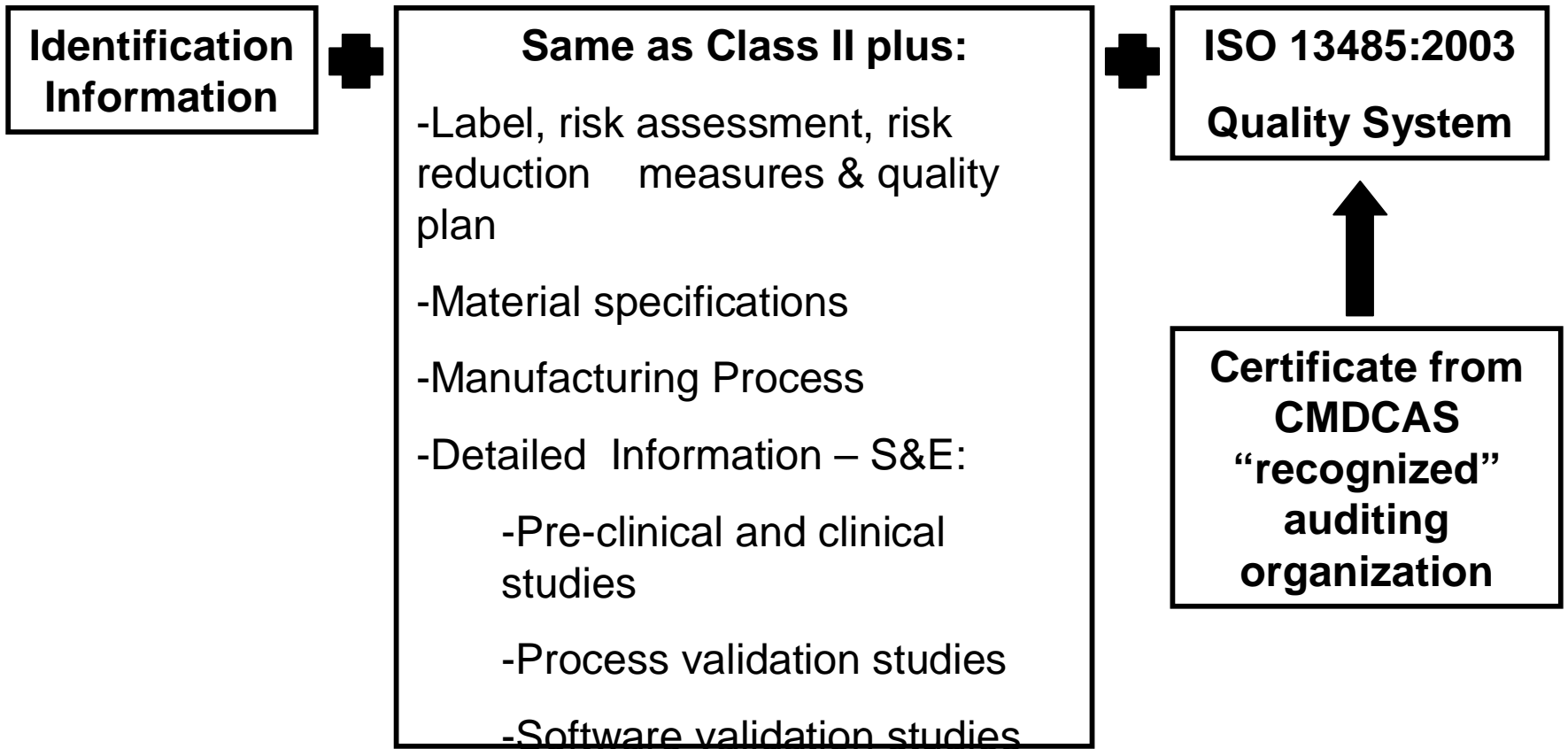
# DEVICE LICENCE CLASS III

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# DEVICE LICENCE CLASS IV



# QMS IN THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES: WHAT ARE THE QMS REQUIREMENTS?

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Depending on the risk, the QMS under which a device is

- Manufactured shall satisfy ISO 13485:2003  
*(Class II devices)*
  - Design and development can be excluded
- Designed and manufactured shall satisfy ISO 13485:2003 *(Class III & IV devices)*

# QMS IN THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES: WHAT ARE THE QMS REQUIREMENTS?

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## Major features of ISO 13485

- Specifies the requirements for the QMS that can be used by an organization for the design and development, production, installation and servicing of medical devices
- Covers areas such as
  - Design and development, manufacturing and testing
  - Labelling, storage, transport, packaging and servicing
  - Reporting, preventive and corrective actions
  - Management responsibilities, human resources, infrastructure and work environment
  - Documentation and records
  - Internal audits and improvement
- Does not specify how to do an activity, but require procedures as to how the activities are done and controlled
- Requires the inclusion of all applicable regulatory requirements in the QMS



# QMS IN THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES: REGISTRAR'S RELATIONSHIP WITH MANUFACTURERS

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- Manufacturer obligated to select a registrar recognized by HC in order to comply with the Canadian QMS requirements
  - Registrar provides third party auditing and certification services to manufacturer under specific conditions defined by HC
  - HC not involved in fee or service arrangements between parties
- Registrar not allowed
  - To provide advice, consulting services or interpretations on the MDR
  - To act as the manufacturer's representative with regards to regulatory issues

# QMS IN THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES: REGISTRAR'S RELATIONSHIP WITH HEALTH CANADA

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- Registrars are recognized by HC as per the conditions set out in the in MDR (§ 32.1)
  - Provisions for de-recognition (§ 32.5)
- Initial and maintenance of recognition of registrars is done through the Medical Device Conformity Assessment System (CMDCAS)
- Registrar's activities leading to the initial and maintenance of certification of medical device manufacturers QMS are controlled by provisions set out the MDR and CMDCAS
- HC does not charge a fee for recognition
  - Fees are charged by the Standards Council of Canada (SCC)

# QMS IN THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES: REGISTRAR'S RELATIONSHIP WITH HEALTH CANADA

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- Registrar not given any regulatory powers
- Registrar's work is limited to QMS and does not include the authority (e.g.)
  - To classify devices, or provide advice in that regard
  - To assess the scientific, technical or clinical data related to the safety & effectiveness provisions of the MDR (§ 10-20)
  - To review, assess or interpret any information related to the compliance of a manufacturer to the MDR
  - To determine the compliance of a manufacturer to the provisions of the MDR
  - Assess the contractual arrangement or activities of a manufacturer related to HC *Guidance for industry - Private Label medical devices*

# REGISTRARS AND THIRD PARTY AUDITS PERFORMED UNDER CMDCAS: WHO ARE THEY?

## Recognized registrars general characteristics

- 5 % Canadian, 85 % foreign
  - No requirement to be incorporated in Canada or maintain a Canadian office
- 75% Notified Bodies
- More than 500 CMDCAS qualified auditors worldwide
  - 90 % outside of Canada
- Can provide service directly or via alliances/  
subcontracting agreements throughout the world
- Can perform joint audits to meet Canadian & various  
countries regulatory schemes, such as CE marking



# REGISTRARS AND THIRD PARTY AUDITS PERFORMED UNDER CMDCCAS: WHO ARE THEY?

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## Participants

- ITS
- KEMA
- LRQA
- LGA
- QMI
- TÜV America
- TÜV RNA
- G-MED
- UL Inc.
- NSAI
- DQS
- BSI
- SGS
- RWTUV
- AMTAC



# REGISTRARS AND THIRD PARTY AUDITS PERFORMED UNDER CMDCCAS: AUDIT PROCESS

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## Audits under CMDCCAS

- Are different from compliance inspections
- Are performed in accordance with
  - ISO Guide 62 and IAF guidance to Guide 62
  - ISO 19011
    - The registrar must take into account any additional HC requirements impacting on the audit process described in ISO 19011



# BUREAU CONTACTS

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