

Decontamination and Reprocessing of Medical Devices in Hospital Authority: Standard and Practice

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Sterilization of Surgical Instruments: From Basic to Advancement

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Content

- Key Driver for Changes
- Where is HA now?
- The Way Forward

A close-up photograph of a hand placing a wooden block with the letter 'C' on top of a block with the letter 'G'. The blocks are arranged in a row on a light-colored wooden surface, spelling out the word 'CHANGE'. The background is a soft, out-of-focus brown. The entire image is framed by a white border with a thin green line inside, and two dark brown horizontal bars are visible on the left and right sides of the frame.

C H A N G E

Key Driver for Changes

- The Australian Council on Healthcare Standards (ACHS) Accreditation Survey in December 2009
- Issues required urgent attention
 - High usage of flash sterilization across hospitals
 - Lack of clear segregation of clean and dirty zones
 - Inconsistency in service governance
 - Variations in the technical standards and requirements applied
 - Lack of effective tracking and tracing of surgical instrument

Task Force on Sterilization Standard of Operating Theater (OT)



Task Force on Sterilization Standard of OT

Service improvement focus and targets

- Eliminate flash sterilization as routine practice
- Eliminate the use of Cidex for rigid endoscope for entry into sterile body cavities
- Develop corporate-wide tracking and tracing system
- Conduct a **consultancy study** to propose plan to enhance disinfection and sterilization of reusable surgical instruments in HA

External Consultancy Study 2011/12

Key Recommendations in the Areas

- A. Governance Structure
- B. Corporate Guidelines on Disinfection and Sterilization
- C. Corporate-wide Instrument Tracking and Tracing System
- D. Linen Wrappers and Drapes

A. Governance Structure

- High-level governance structure to sustain the enhancement and quality assurance of sterilization
- A cluster sterilisation lead responsible for operational governance and QA
- Define a reporting line (e.g. to the CCE / deputy CCE). Clear responsibility and accountability
- A centralized CSSD to consolidate the management of instrument reprocessing and other sterilization services
- Service managed by a skilled, competent and adequately staffed team

B. Corporate Guidelines on Disinfection and Sterilization

- Revise HA Guidelines on the Disinfection and Sterilization of Reusable Medical Devices for OT
- Include recommendations concerning environmental considerations for facilities, such as ISO Class 8, to ensure clean rooms and air quality standards

C. Corporate-wide Instrument Tracking and Tracing System

- Develop a corporate-wide electronic surgical instrument tracking and tracing system

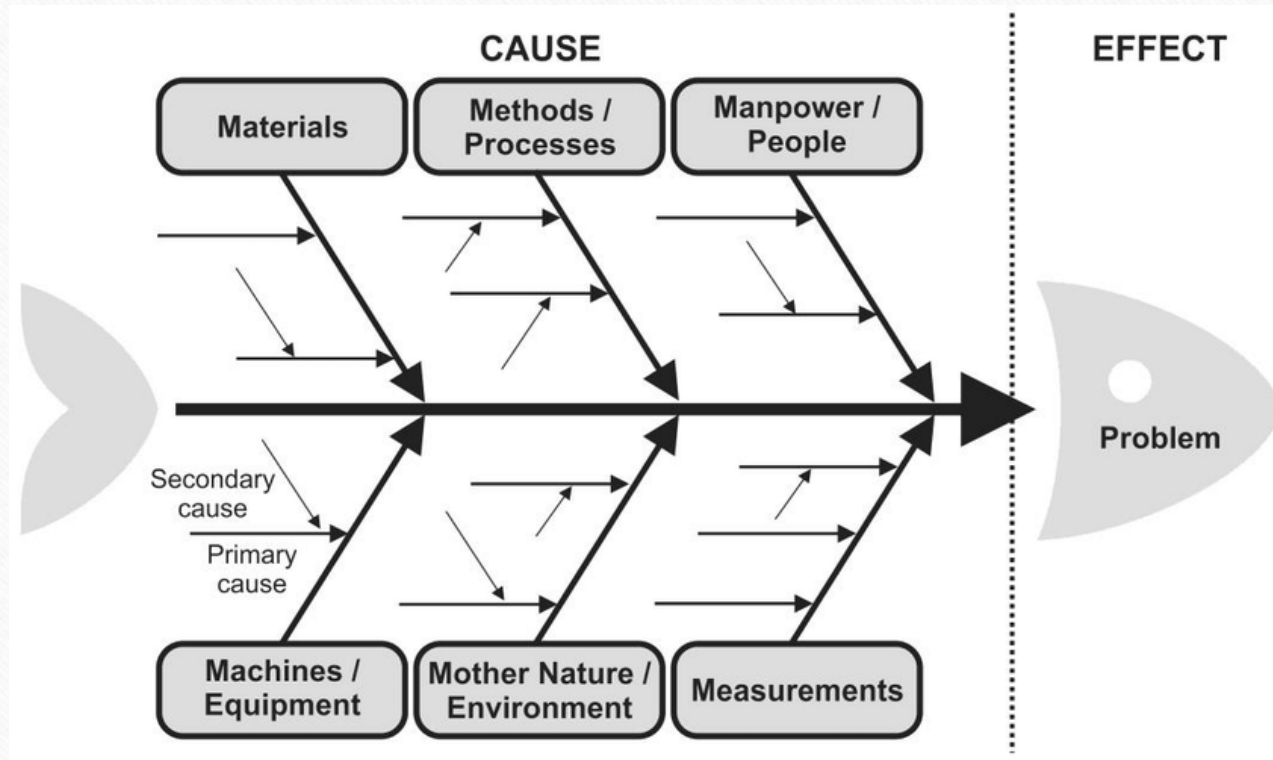
D. Linen Wrappers and Drapes

- Replace linen wrappers and drapes by disposable

Internal Audit on Sterilization and Disinfection 2014/15

- Review the compliance of CSSDs with the External Consultancy Report and the Guidelines
- Total 20 hospitals with CSSDs audited
- All CSSDs met the mandatory requirements

Where is HA Now?



Where is HA Now?

- A. Trained People
- B. Improved Environment
- C. Upgraded Machines / Equipment
- D. Up-to-Standard Materials
- E. Methods / Processes in accordance with international standards
- F. Measurements for Improvement


A. Trained People

Service Core Group (Sterile Supply Services)



A. Trained People

Service Core Group (Sterile Supply Services)

 醫院管理局 HOSPITAL AUTHORITY	Hospital Authority Head Office	Document No.	COC-G(N) Approved Paper 34/2019
	Standard of Routine Monitoring of Steam Sterilization	Issue Date	06/12/2019
		Review Date	06/12/2022
		Approved by	COC-G(N)
		Page	1 of 5

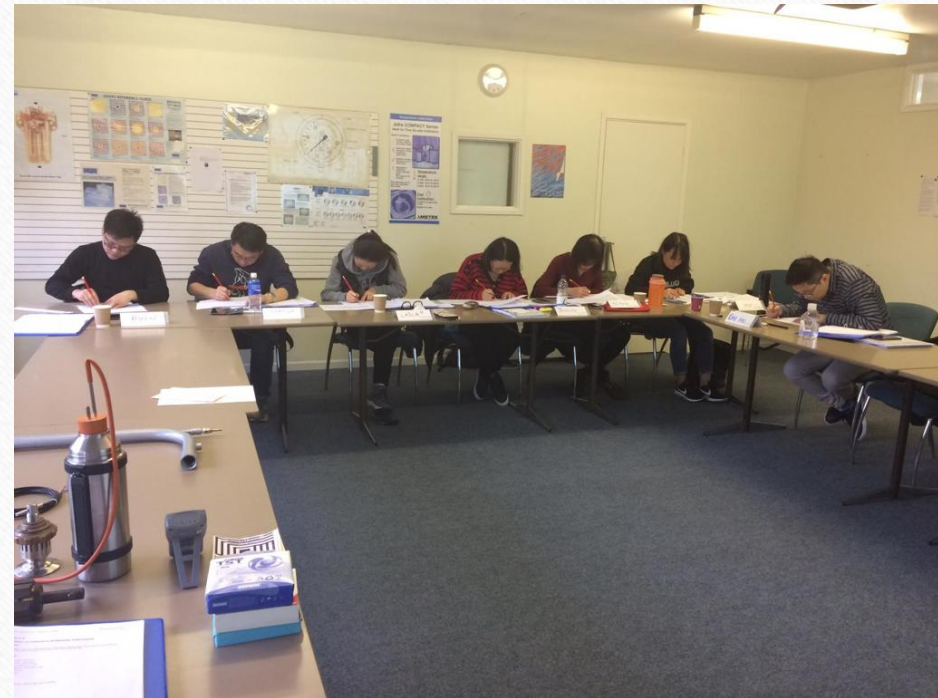
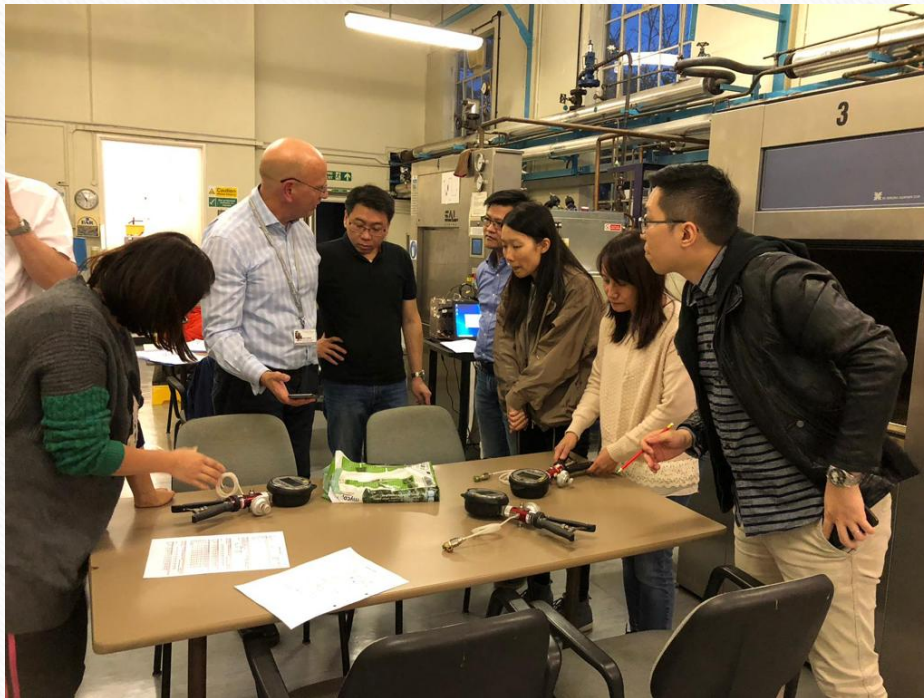
Standard of Routine Monitoring of Steam Sterilization

Version	Effective Date
1.0	06/12/2019

Document Number	COC-G(N) Approved Paper 34/2019
Author	Service Core Group (Sterile Supply Services)
Custodian	NSD / HOCS
Approved/ Endorsed By	COC-G(N)
Approval Date	06/12/2019
Distribution List	HA – All Nursing Staff

A. Trained People

Overseas Corporate Scholarship Programs



A. Trained People Commissioned Training Courses



B. Improved Environment

- Reprocessing facilities should be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities
- All newly built or renovated units should follow the facility requirements

B. Improved Environment

Segregation of Facilities into Clean and Dirty Areas



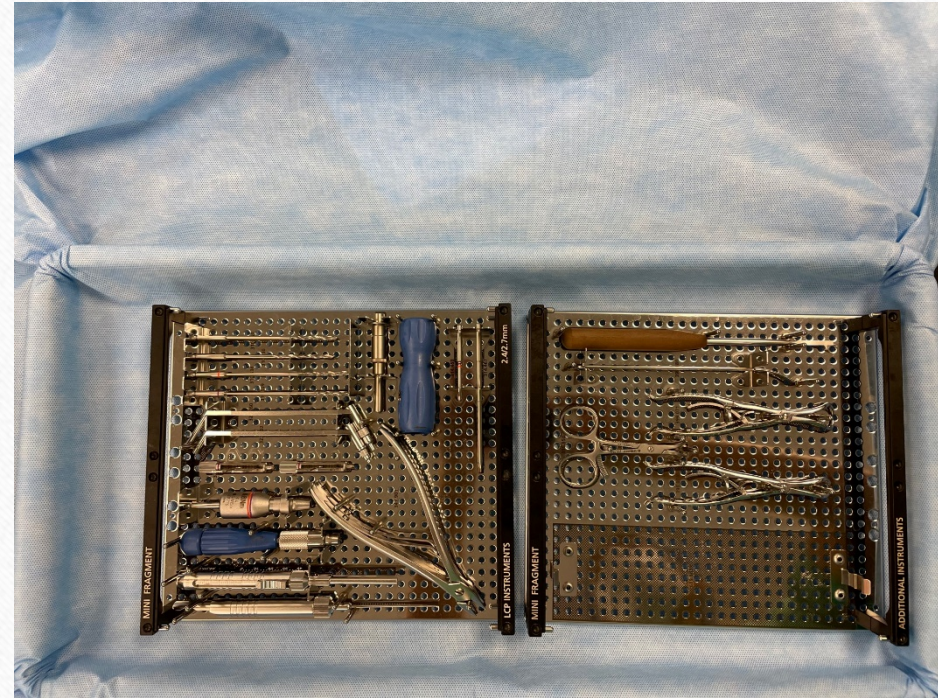
B. Improved Environment ISO Class 8 Cleanroom



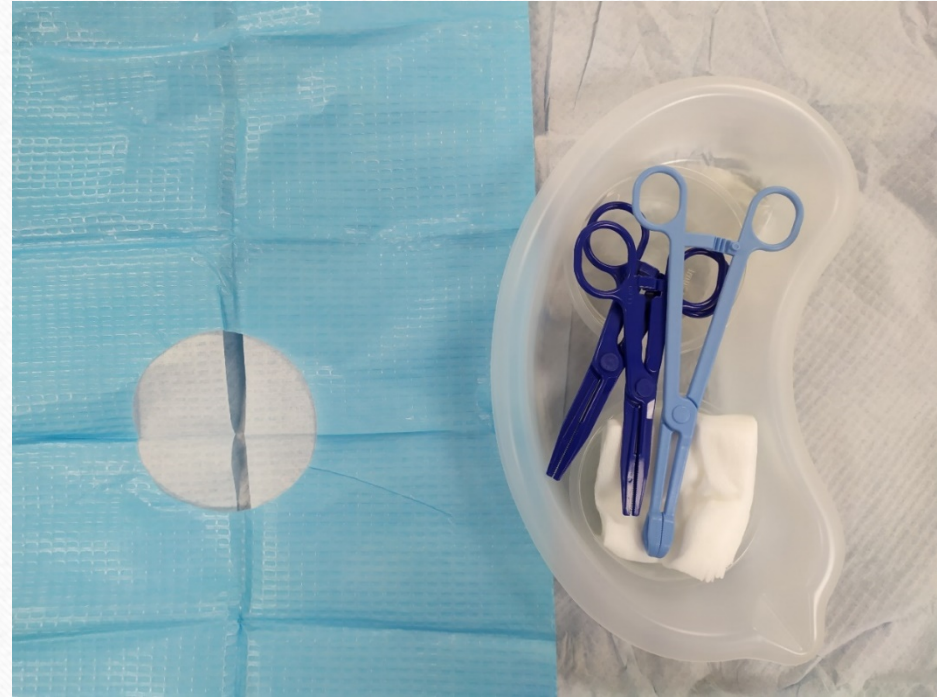
C. Upgraded Machines/Equipment Water Treatment Systems



D. Up-to-Standard Materials Disposable Wrappers




D. Up-to-Standard Materials Disposable Drapes for OT



E. Methods/Processes

Revised Corporate Guidelines on Disinfection and Sterilization

 醫院管理局 HOSPITAL AUTHORITY	Hospital Authority Head Office	Document No.	HAHO-COM-GL-TFS-001-v03
	Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre	Issue Date	09/08/2019
		Review Date	16/08/2022
		Page	1 of 46

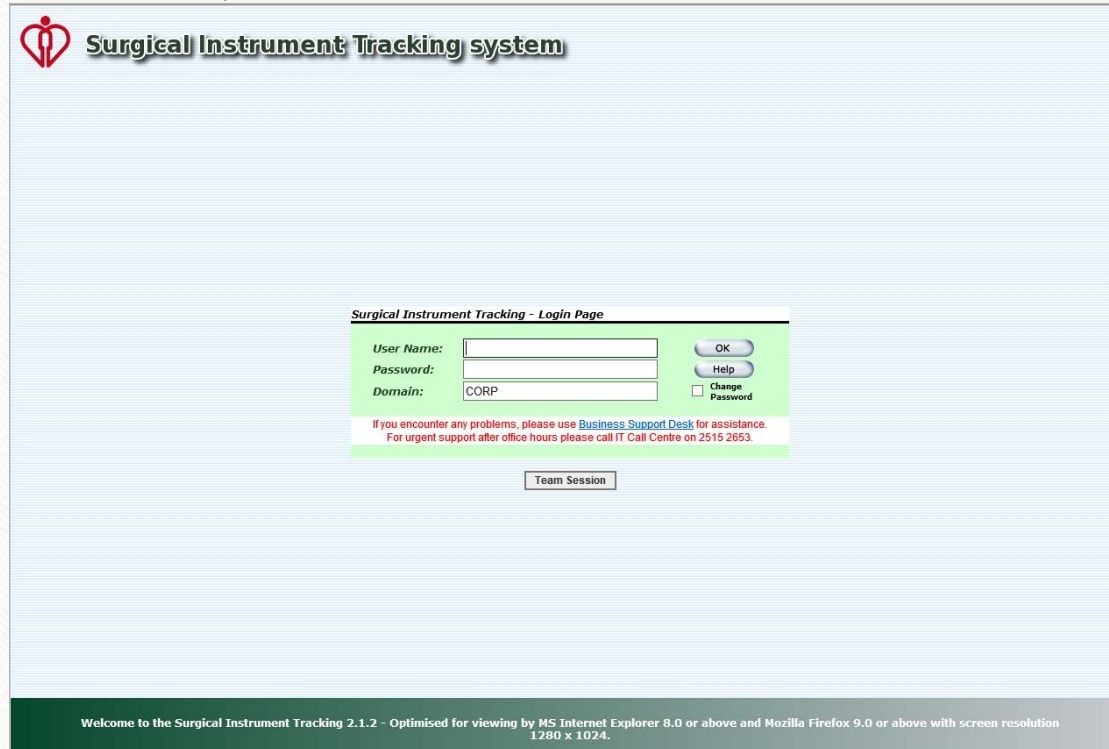
Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre

Version	Effective Date
3.0	16/08/2019

- ISO 13485 Quality Management System
- ISO 17665 Steam Sterilization
- ISO 15883 Washer Disinfector
- ISO 14644 Cleanroom
- ISO 11607 Packaging Materials

E. Methods/Processes

Corporate-wide Instrument Tracking and Tracing System



The screenshot displays the login interface for the Surgical Instrument Tracking system. At the top left, there is a red heart icon with a white 'S' inside, followed by the text 'Surgical Instrument Tracking system'. The main content area is light blue. In the center, there is a white box titled 'Surgical Instrument Tracking - Login Page'. Inside this box, there are three input fields: 'User Name:', 'Password:', and 'Domain:'. The 'Domain:' field has 'CORP' entered. To the right of these fields are three buttons: 'OK', 'Help', and 'Change Password'. Below the input fields, there is a small red text block: 'If you encounter any problems, please use [Business Support Desk](#) for assistance. For urgent support after office hours please call IT Call Centre on 2515 2653.' At the bottom of the white box is a 'Team Session' button. The footer of the page is dark green and contains the text: 'Welcome to the Surgical Instrument Tracking 2.1.2 - Optimised for viewing by MS Internet Explorer 8.0 or above and Mozilla Firefox 9.0 or above with screen resolution 1280 x 1024.'

Surgical Instrument Tracking system

Surgical Instrument Tracking - Login Page

User Name:

Password:

Domain:

OK

Help

☐ Change Password

If you encounter any problems, please use [Business Support Desk](#) for assistance.
For urgent support after office hours please call IT Call Centre on 2515 2653.

Team Session

Welcome to the Surgical Instrument Tracking 2.1.2 - Optimised for viewing by MS Internet Explorer 8.0 or above and Mozilla Firefox 9.0 or above with screen resolution 1280 x 1024.

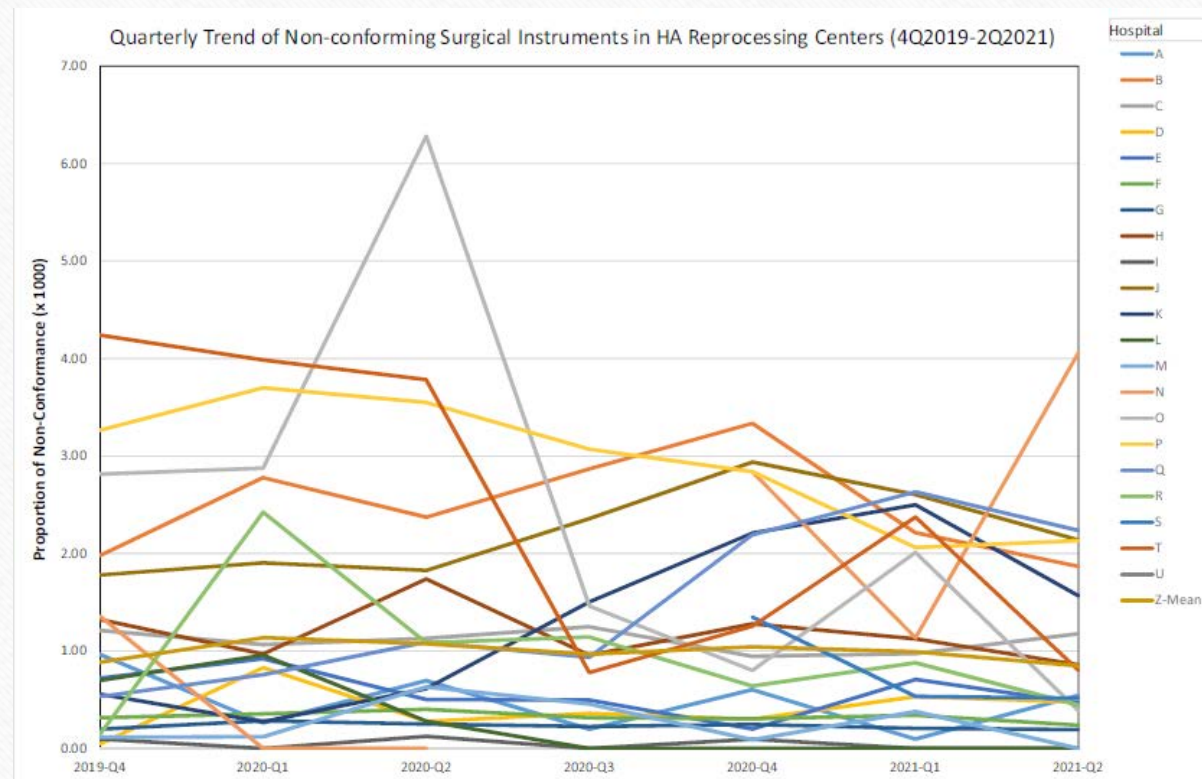
F. Measurements for Performance Benchmarking for Quality Improvement

	Non-conformity		Non-conformity
1	Wet Pack	7	Defect in External Chemical Indicator
2	Torn / Damaged Package	8	Missing Internal Chemical Indicator
3	Incorrect Set Label	9	Incorrect Instrument / Implant
4	Missing Warning Sheet	10	Dirty Instruments
5	Incorrect Packing	11	Damaged Instruments / Missing Parts
6	Incorrect Packing (Container)	12	Incorrect Assembly of Instruments

F. Measurements for Performance Benchmarking for Quality Improvement

	Non-conformity	Definition
1	Wet Pack	All package should be dry and free from water
		Instruments and instrument trays should be dry inside the package
2	Torn / Damaged Package	The package should be intact and clean

F. Measurements for Performance Benchmarking for Quality Improvement



Key Successful Factors

- Governance: Top-down and Bottom-up
- Train your people
- Guidelines, Guidelines and Guidelines

The Way Forward

- Governance structure
- Validation of cleaning, disinfection and sterilization processes
- Sterilization of flexible endoscopes

The Way Forward

- Obtain accreditation specifically for medical device reprocessing (such as ISO 13485)

INTERNATIONAL
STANDARD

**ISO
13485**

Second edition
2003-07-15

**Medical devices — Quality management
systems — Requirements for regulatory
purposes**

*Dispositifs médicaux — Systèmes de management de la qualité —
Exigences à des fins réglementaires*

Thanks for
HAHO and Cluster Management
Support
