

# CSA & KMS

## Centrale Sterilisatie Afdeling Kwaliteitsmanagementsysteem

*QMS = Quality Management System*

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# presentatie

- inleiding
- food for thought
- vraag en antwoord

# FOOD FOR THOUGHT

- QMS : basisbegrippen
- aanzetten tot reflectie
- industrie versus ziekenhuis
- “means and ends”
- QMS legt fundamenten

# QMS requirements

- establish
- document
- implement
- maintain
- continually improve its effectiveness

**QM**

total picture

**PROCEDURES**

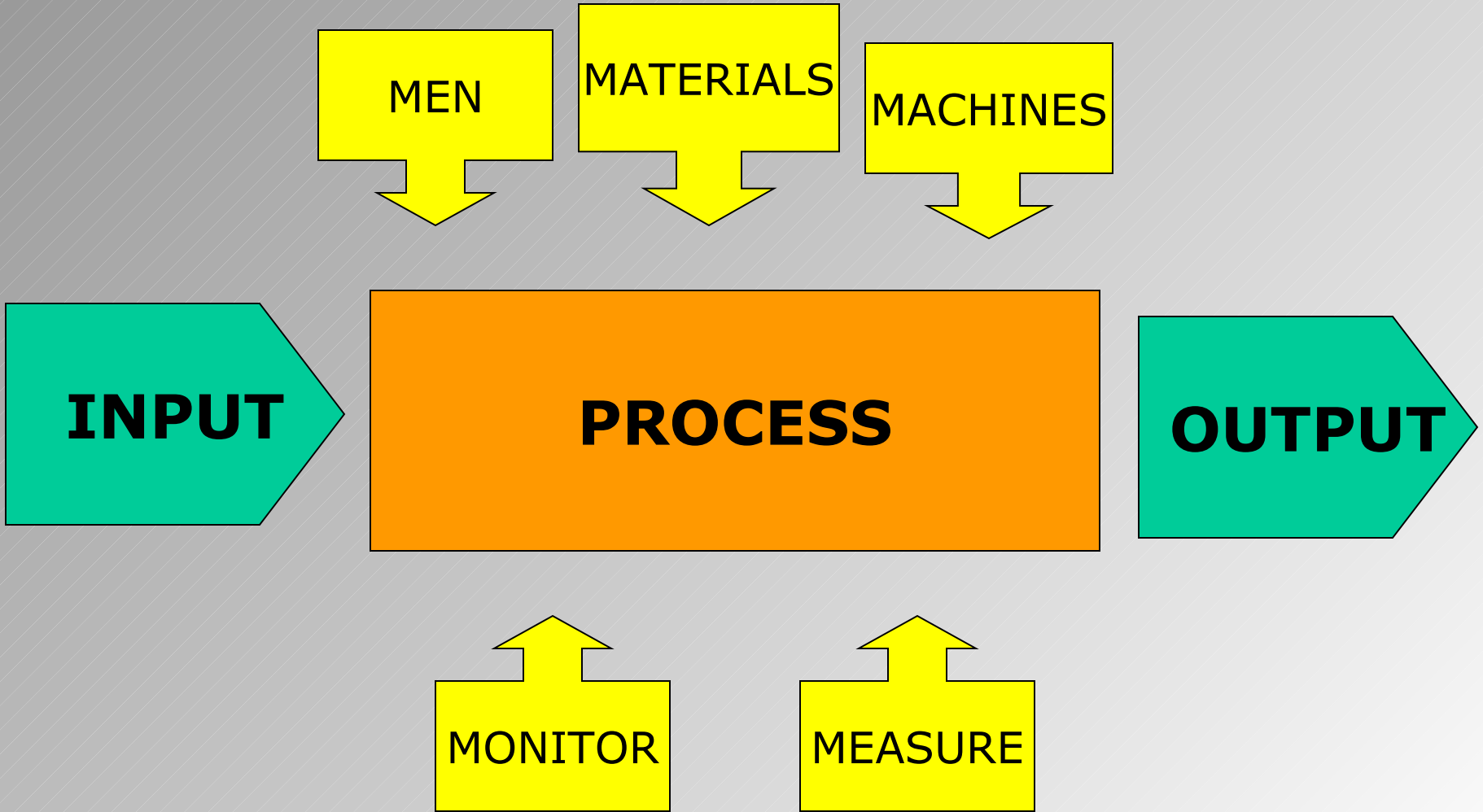
what

**WORK INSTRUCTIONS**

how

**FORMS**

quality  
registration



**EFFICIENCY**

**EFFECTIVENESS**

**INPUT**

**PROCESS**

**OUTPUT**

# EFFECTIVENESS

- “doing the right things”
- ability to achieve the desired results



# EFFICIENCY

- “doing the things right”
- have we maximized our resources ?

# ISO standards

- NBN EN ISO 9001:2000
- NBN EN ISO 13485:2003
- NBN EN ISO 14937:2000

# NBN EN ISO 9001:2000

- *Quality Management Systems*
- *Requirements*

# NBN EN ISO 13485:2003

- *Medical Devices*
- *Quality Management Systems*
- *Requirements for regulatory purposes*

# NBN EN ISO 14937:2000

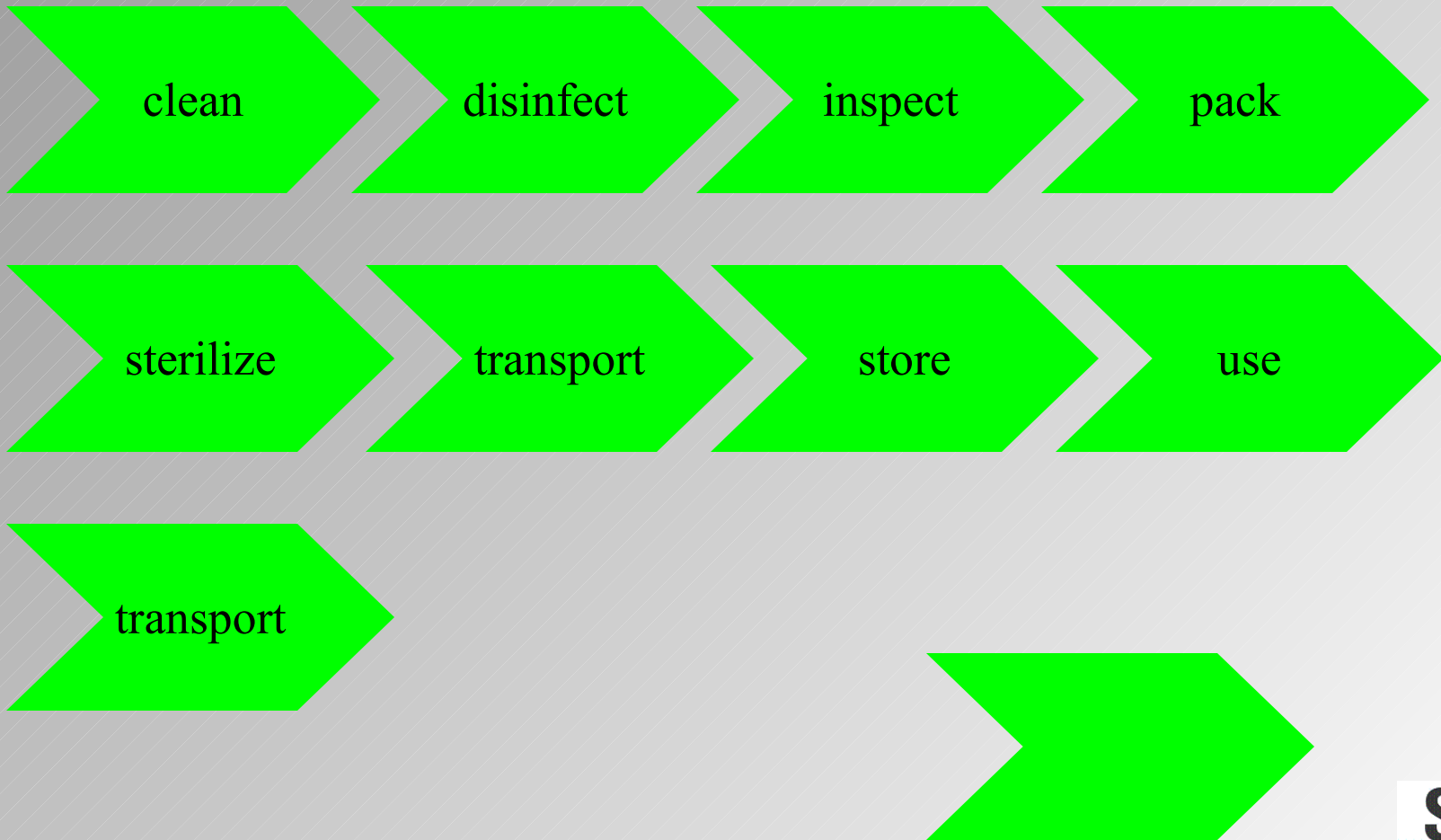
- *Sterilization of health care products*
- *General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

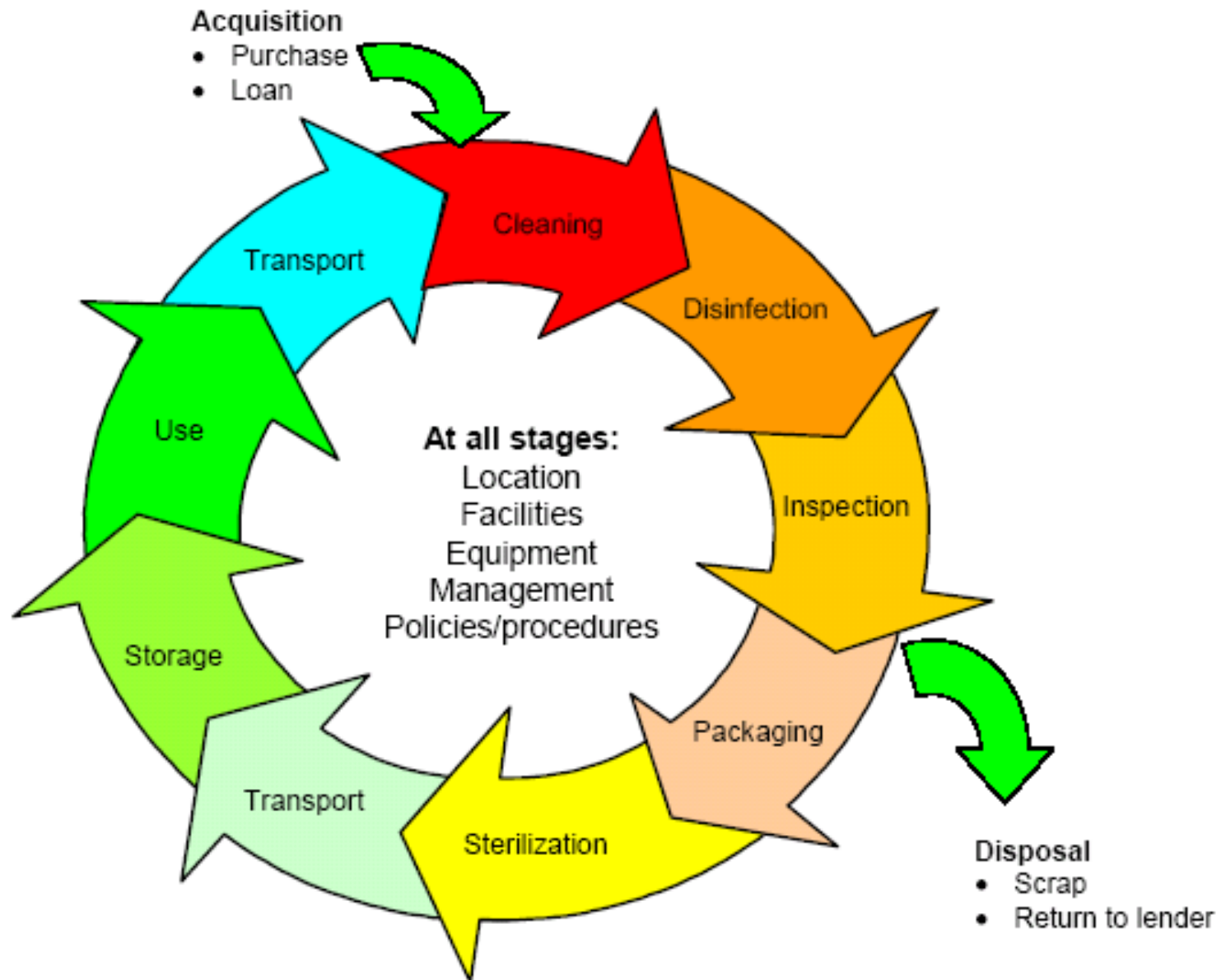
**CSA OUTPUT**

**STERILE**

**PRODUCTS**

# CSA process breakdown



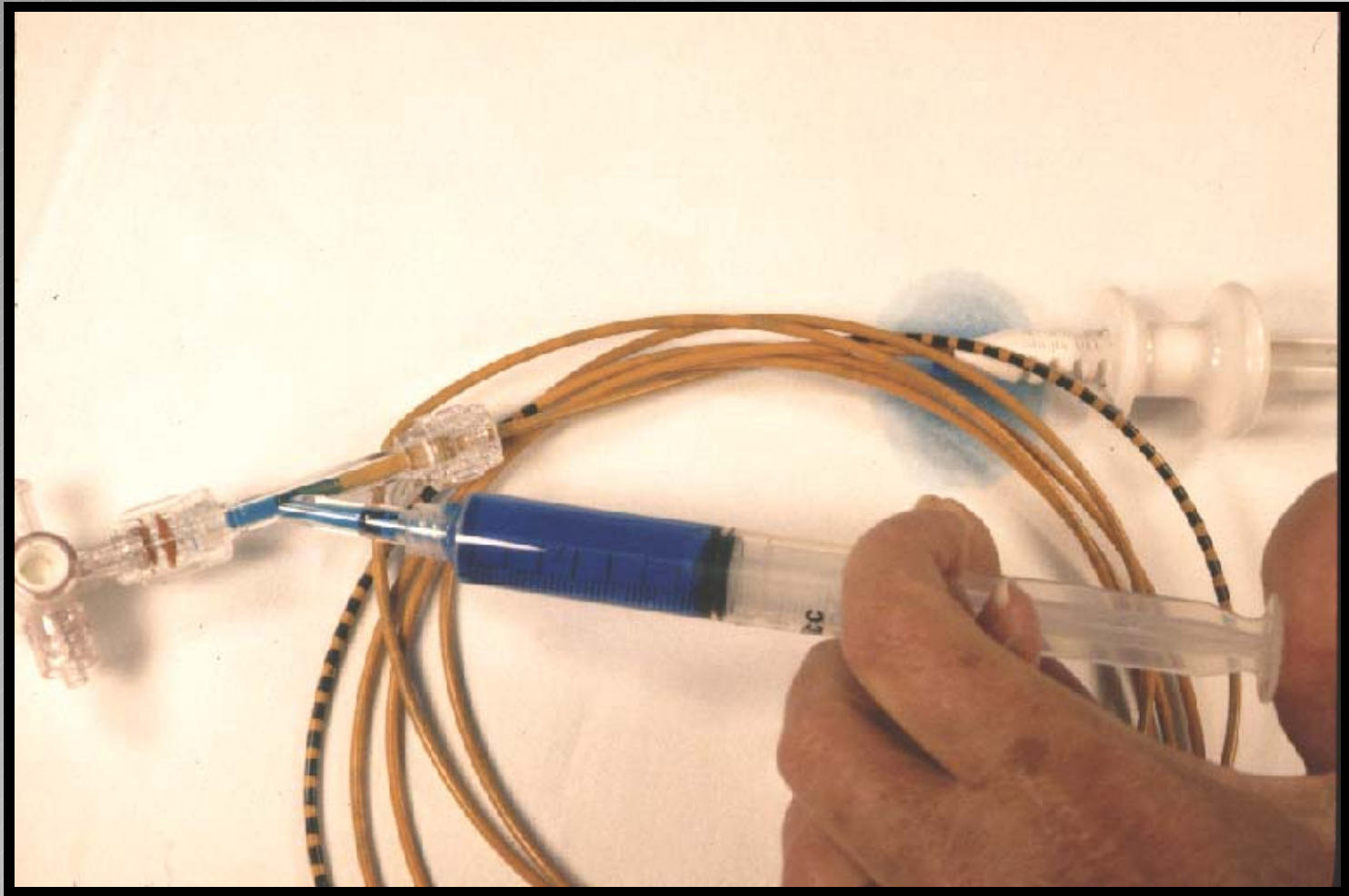


source : MHRA document



# CSA : case study

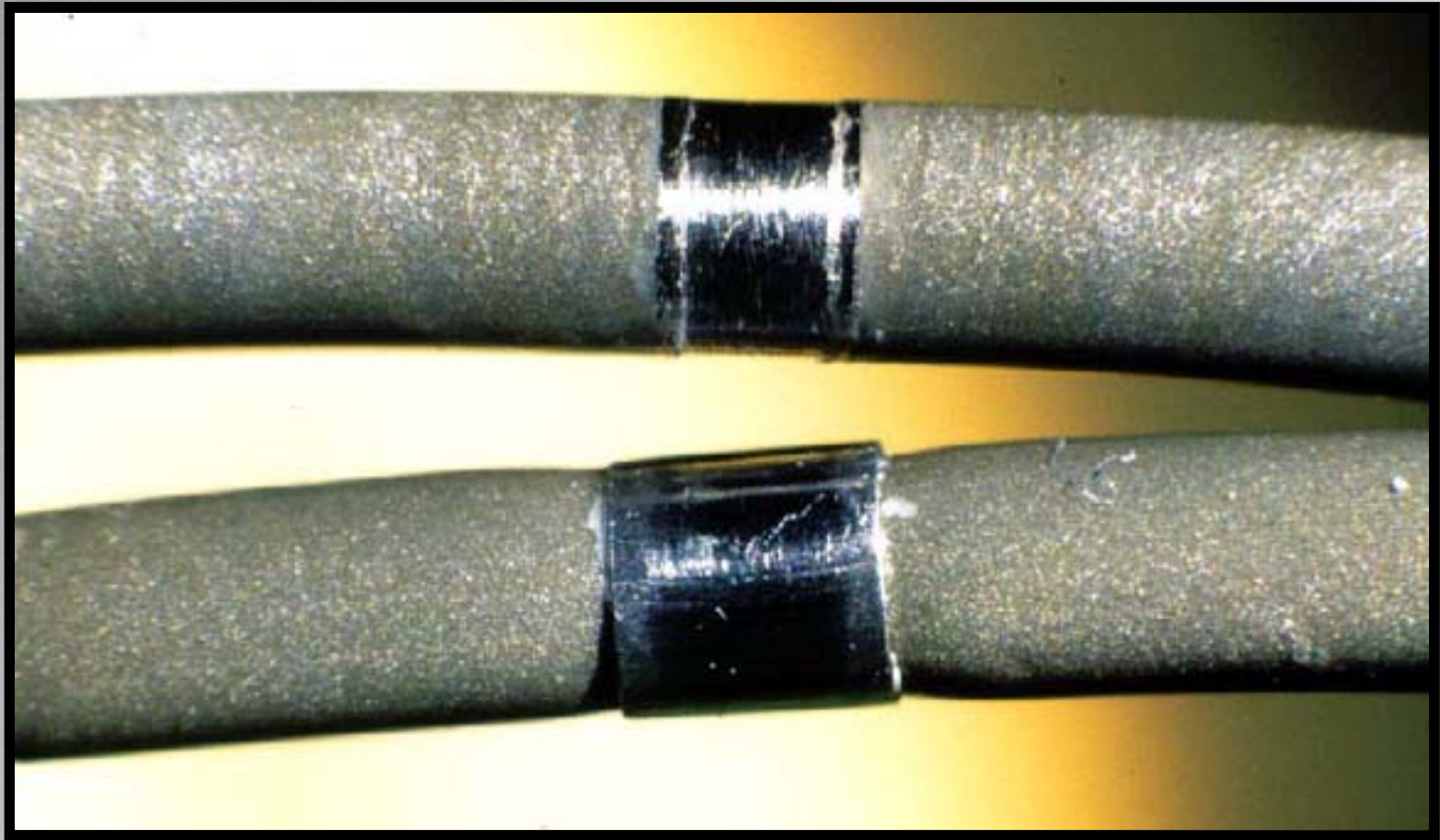
- SUD : single use devices
- resterilize SUD ?
- effectiveness of QMS / process ?
- efficiency of QMS / process ?



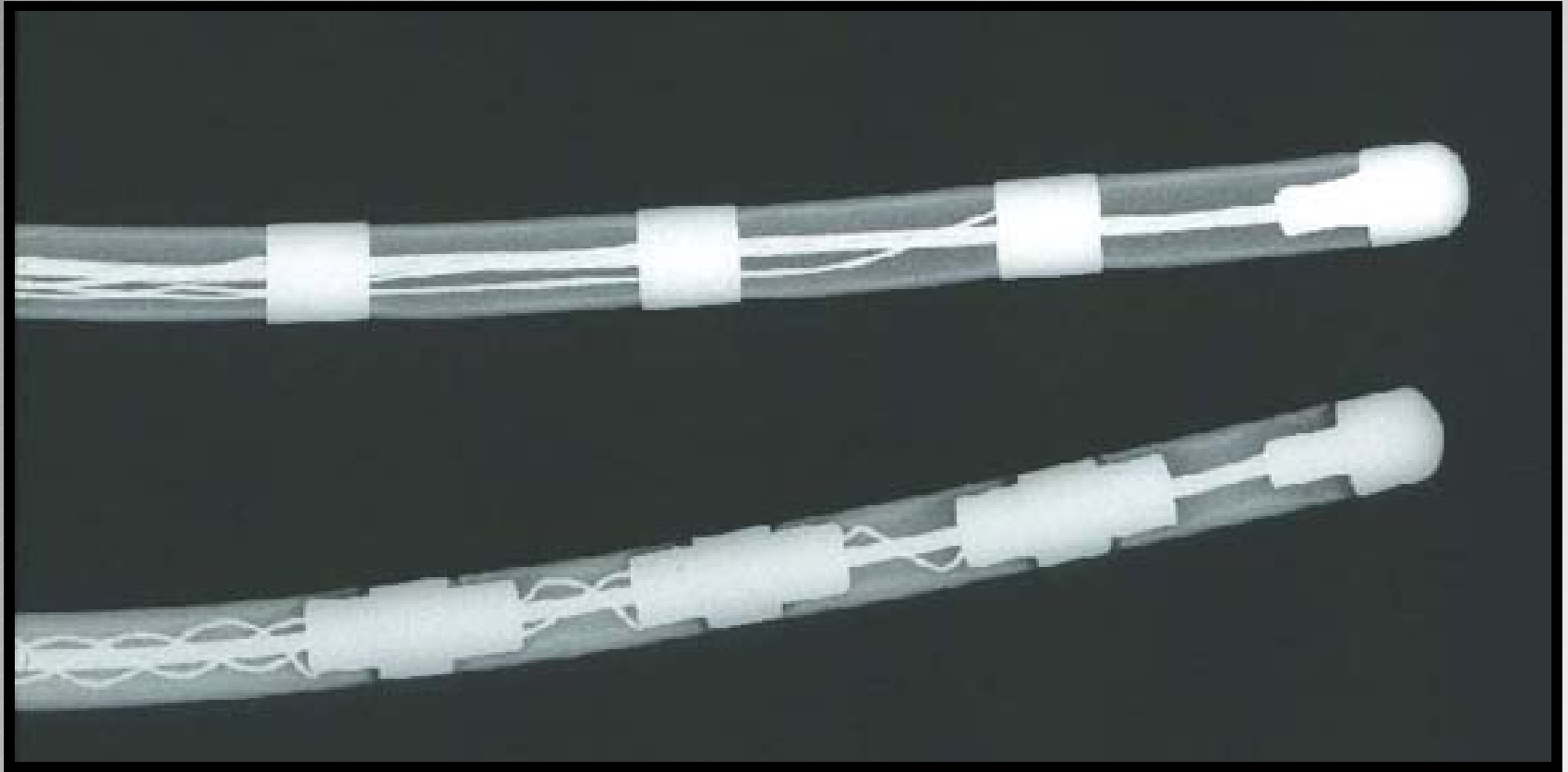
source : FDA website : reuse of SUD's



source : FDA website : reuse of SUD's



source : FDA website : reuse of SUD's



source : FDA website : reuse of SUD's



source : FDA website : reuse of SUD's

# ISO14937:2000

- quality system
- sterilizing agent characterization
- process & equipment characterization
- product definition
- process definition
- validation : IQ OQ PQ
- routine monitoring & control
- product release
- maintaining process effectiveness

CSA	MD manufacturer
unlimited	limited # products
steam, ETO, VHP	steam, ETO, VHP, radiation,
very high time pressure	only at market introduction
based on provided info	known resterilization effects
limited	unlimited resources
not part of	design of medical device
...	...



# Quality Management System

- system certification > < product certification
- ideal situation = functional marriage between QMS and cGMP
- certification = confirmation QMS
- certification = only the start !
- customer requirements plus regulatory and statutory requirements

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**BEDANKT  
VOOR  
UW AANDACHT**