

# “Sterilization in Europe”

Wim Renders

**WFHSS**

# 1. History of sterilization

# History of sterilization



# History of sterilization



# History of sterilization



# History of sterilization



# History of sterilization



# History of sterilization



# History of sterilization



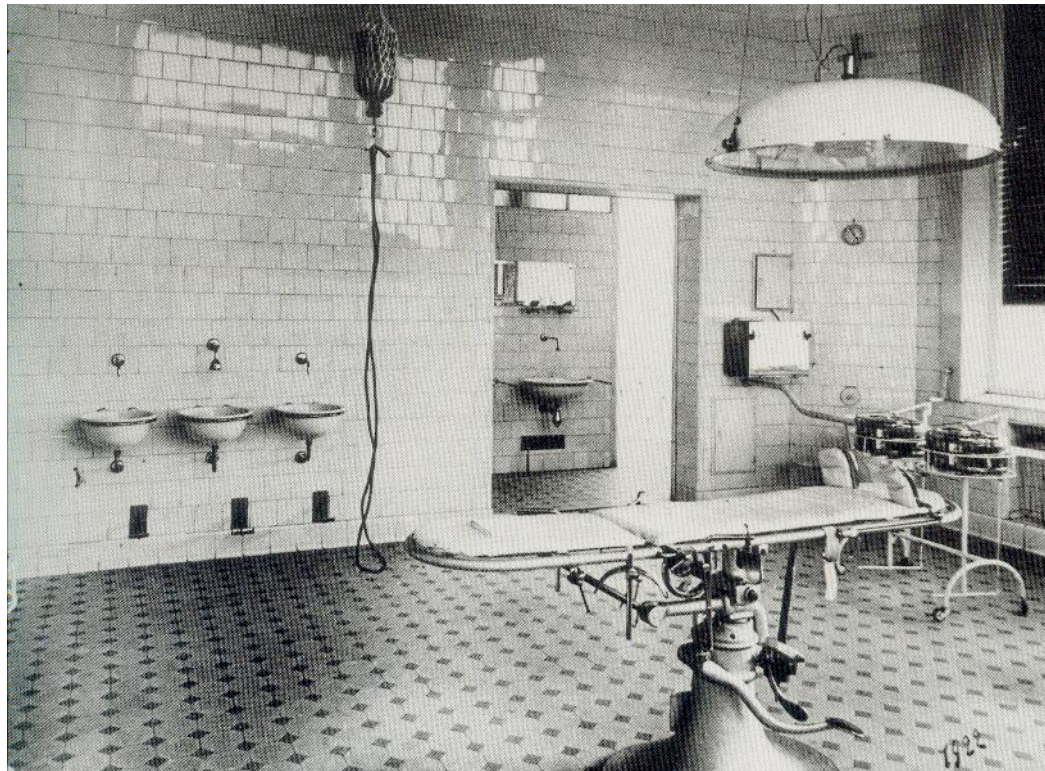
## History of sterilization



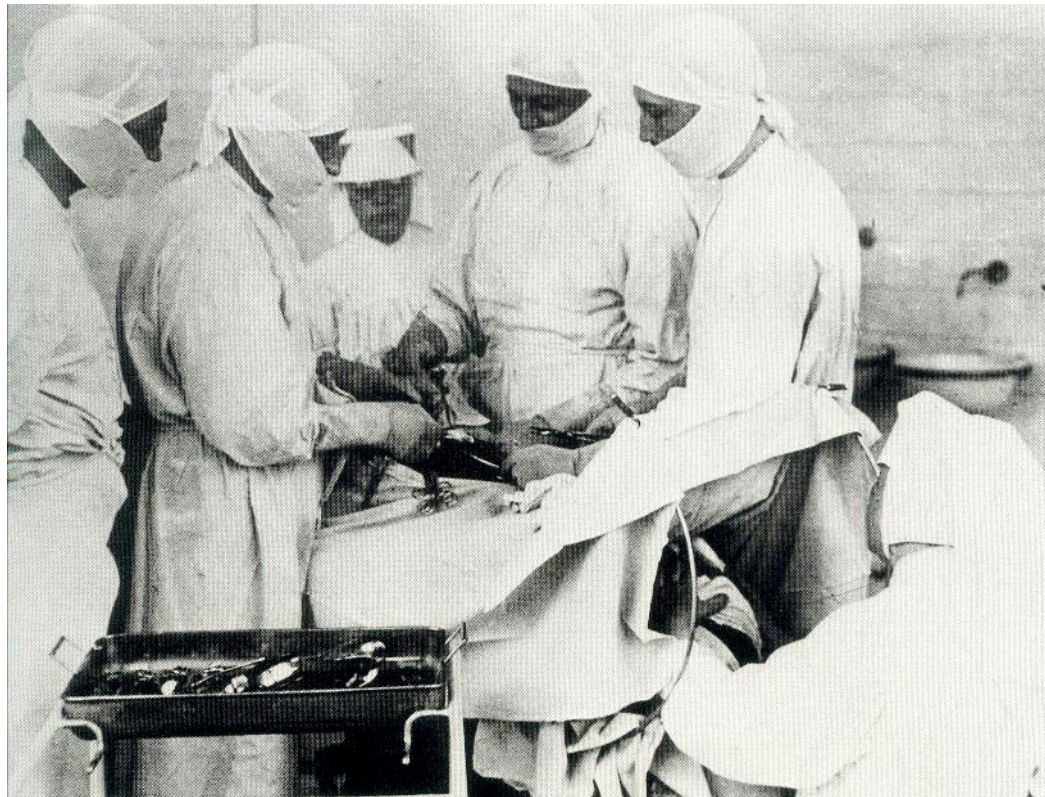
## History of sterilization



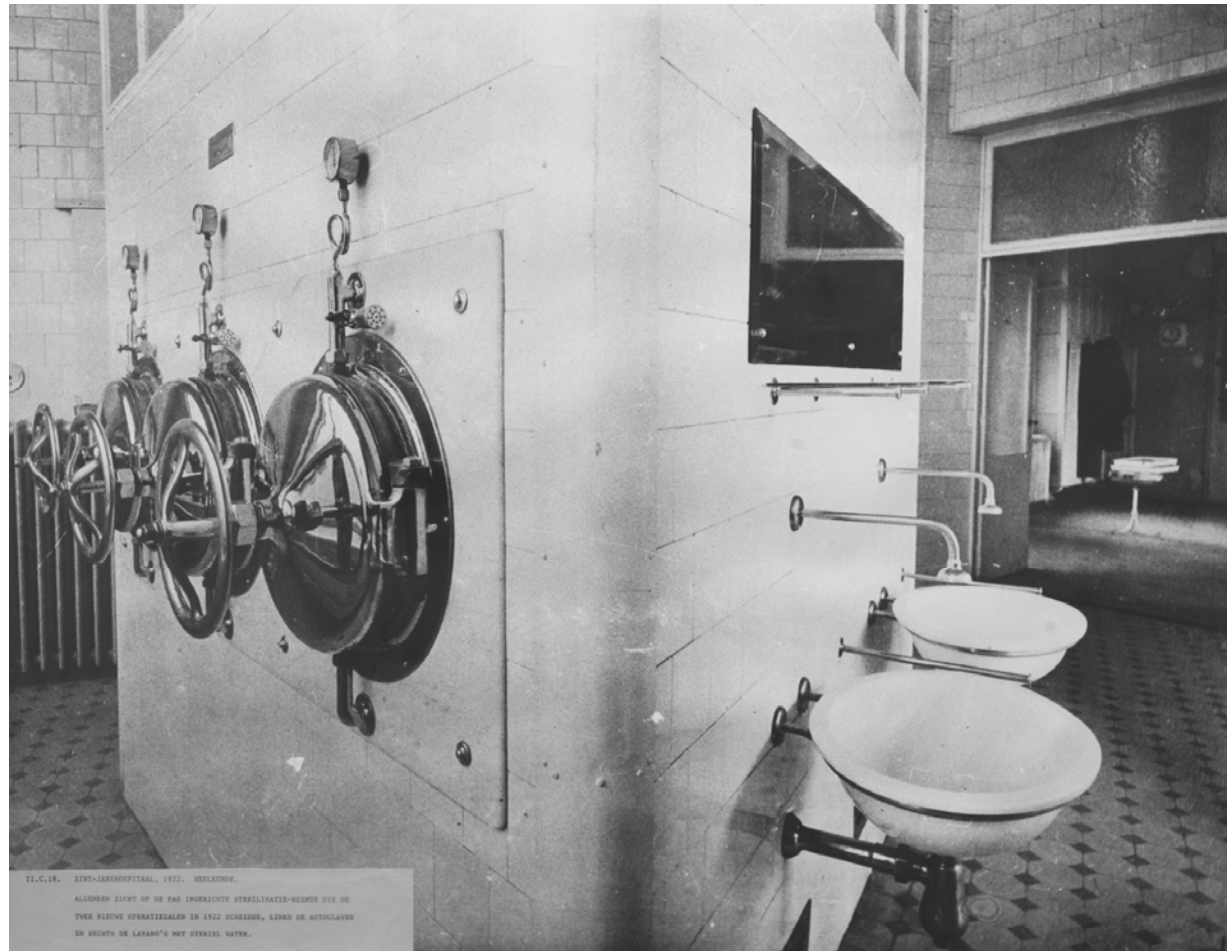
## History of sterilization



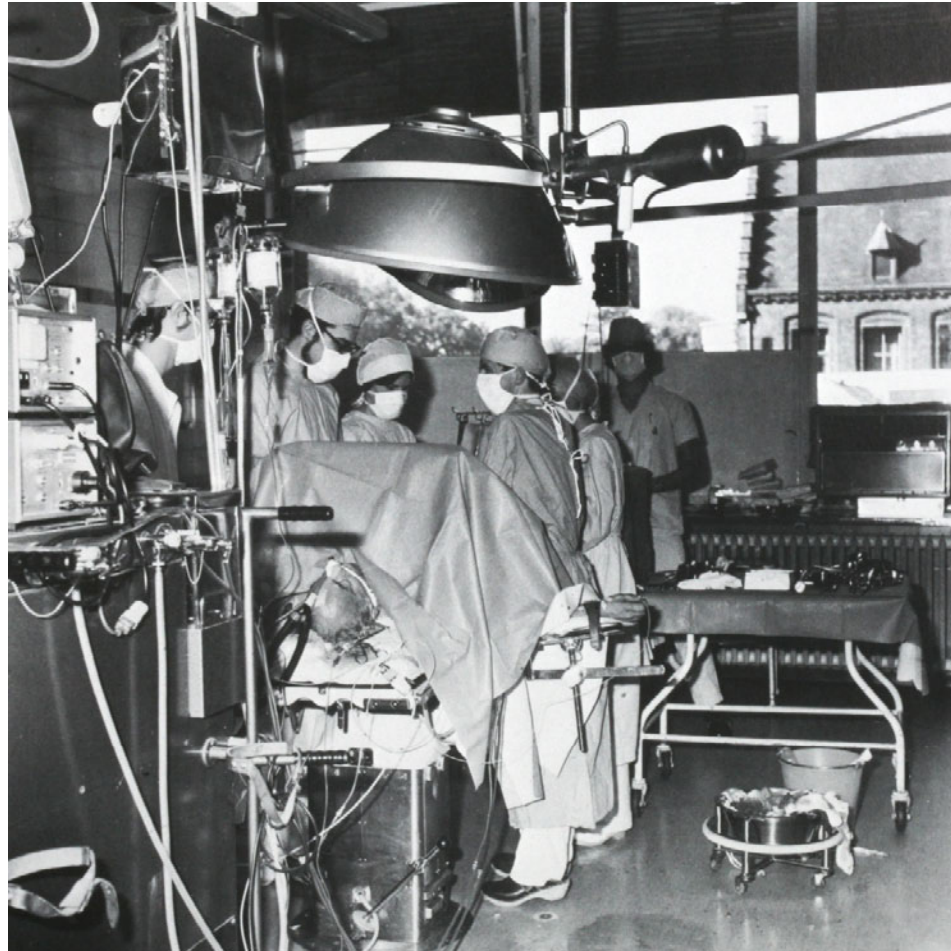
## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization



## History of sterilization





1. History of sterilization
2. The role of the associations
  - National
  - European
  - Global

The quality system which is the most appropriate one for the treatment of medical devices is EN – ISO 13485(2003):

“Quality systems - Medical devices – Particular requirements for the application of EN – ISO 9001: 1994 (revision of EN 46001: 1996).





Adres <http://users.skynet.be/vsz/> Ga naar Koppelingen >>

Hoofverpleegkundige CSA  
Studiedag V.S.Z.



## INHOUD

- BESTUUR
- STATUTEN
- LIDMAATSCHAP
- PROGRAMMA
- LOPENDE ZAKEN
- WERKGROEPEN
- BRIEVENBUS
- ARTIKELS
- ANDERE WEBSITES
- AD VAL VAS
- VERSLAGEN
- EUROPEES FORUM
- COMMERCIELE LINKS



### VERENIGING STERILISATIE IN HET ZIEKENHUIS V.Z.W.



*het doel van de vereniging is kennis uit te wisselen  
over behandeling en sterilisatie van instrumentarium  
en omgaan met steriele medische hulpmiddelen.  
de vereniging wil ook ijveren voor kwaliteitsnormen  
voor de centrale sterilisatieafdeling en voldoende  
financiële armslag om een goede infrastructuur te  
waarborgen.*

Adres <http://www.asterinfo.com/> Ga naar Koppelingen >>

## ASSOCIATION FRANCOPHONE DE STERILISATION asbl




Aster *online*  
*info*

site personnel Webmaster  
[cliquer ici](#)



World Forum for Hospital Sterile Supply

[Home](#) | [Logos](#) | [News](#)

[Members](#) **NEW**  
[Communications](#)  
[Conferences & Congresses](#)  
[Courses & Seminars](#)  
[Questions & Answers](#) **NEW**  
[Discussion Forum](#)  
[CEN](#)  
[Publications](#)  
[Education](#)  
[WFHSS WebShop](#)  
[Industrial Partners](#)  
[Commercial Announcements](#)  
[Related Sites & Links](#) **NEW**  
[Vacancies](#)  
[Humour](#)  
[Guestbook](#)  
[Board Member Section](#) **NEW**

**WFHSS Member Organisations**

Argentina FUDESA »	Australia SRACA »	Austria ÖGSV »
Belgium V.S.Z »	Brazil OBEUNE	Brazil SOBECC »
Bulgaria BulSteri	Chile EPE »	Colombia ACPCE »
Croatia Croatia	Czech Republic CSS »	Denmark DKCS »
France AFS »	Germany DGSV »	Greece GORNA »
Hong Kong HKSSMA »	Hungary HuDiS »	India ICSSA
Ireland IASSM »	Israel ISA »	Italy AIOS »
Japan JSMI »	Japan SCSTS »	Kuwait ICD
Latvia LSHSA	Lithuania CSSA	Macedonia Macedonia
Malaysia MSSA »	Malta SAM	Mexico AMPE »
Netherlands CSC »	Netherlands vDSMH	New Zealand NZSSA »
Norway NFS »	Oman SAO	Poland PSSSM
Portugal ANES »	Romania ROSTERIL	Slovakia SPNN »
Slovenia ZZNS »	South Africa CFSA »	South Korea KACSDN »

**WFHSS Events**

**Annual WFHSS and AIOS Conference 2008**  
4/5/6/7 June 2008 in Milano, Italy  
» [Conference Website](#)  
» **NEW** [Conference Lectures](#)

**Annual WFHSS Conference 2009**  
» date and location to be confirmed



**WFHSS News**

**12 July 2008, 14:17 [GMT]**  
**WFHSS Questions and Answers**  
answer to question 1793: CSSD operational standard

**11 July 2008, 21:00 [GMT]**  
**WFHSS Members**  
**new WFHSS member organization:**  
**KACSDN - Korea Association of Central Supply Department Nurses (South Korea)**

**11 July 2008, 20:30 [GMT]**  
**WFHSS Related Sites & Links**  
link to new WFHSS Member organization KACSDN - Korea Association of Central Supply Department Nurses (South Korea) added

**11 July 2008, 16:29 [GMT]**  
**WFHSS Questions and Answers**  
answer to question 1862: Policy procedure for cssd

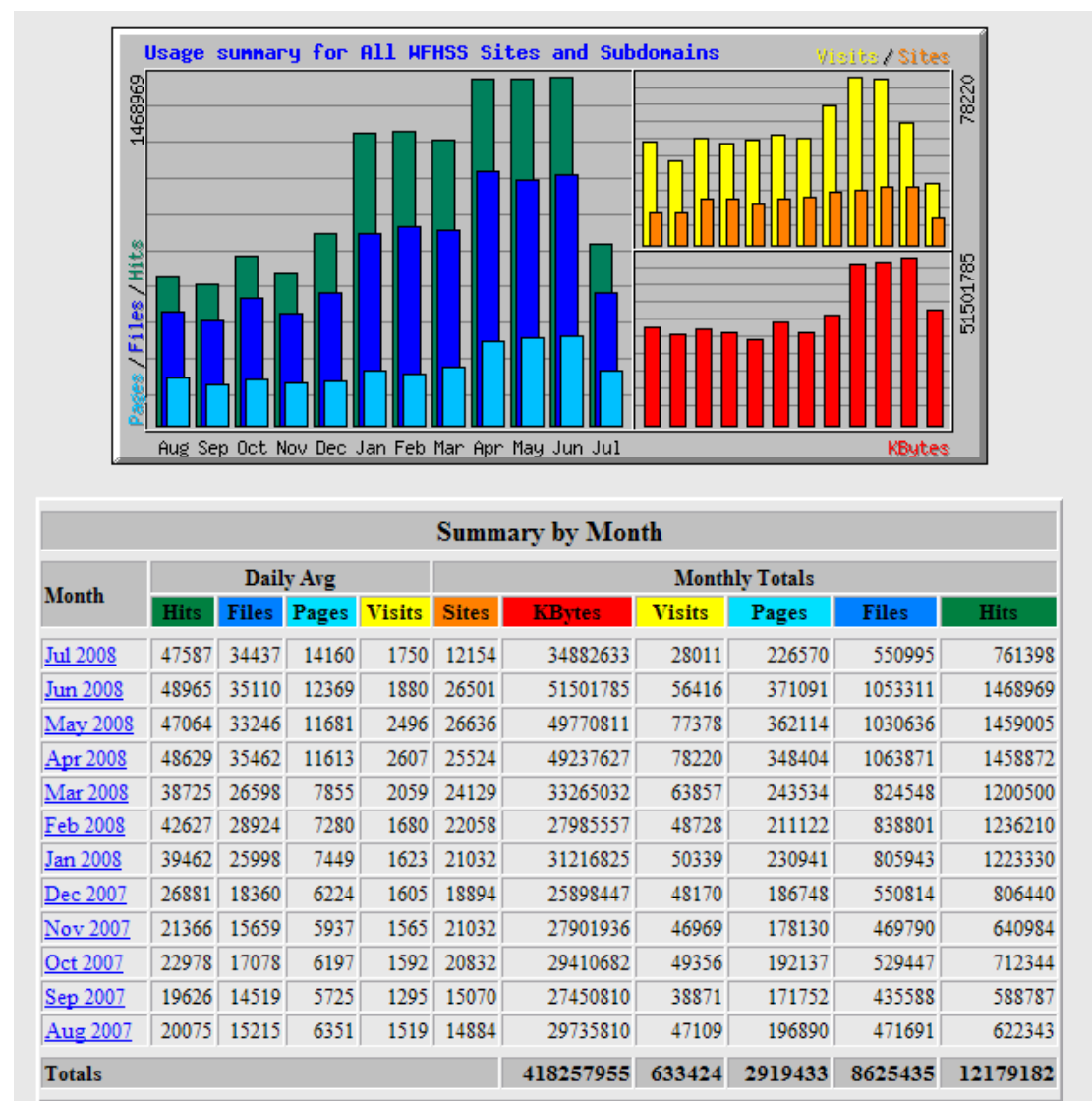
**11 July 2008, 03:15 [GMT]**

**Industrial Partners:**



7129177

## Statistics



## Lillehammer



1. History of sterilization
2. The role of the associations
  - National
  - European
  - Global
3. The Medical Device Directive



31993L0042

## Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

*Official Journal L 169 , 12/07/1993 P. 0001 - 0043*

*Finnish special edition: Chapter 13 Volume 24 P. 0085*

*Swedish special edition: Chapter 13 Volume 24 P. 0085*

ES	CS	DA	DE	ET	EL	EN	FR	IT	LV	LT	HU	MT	NL	PL	PT	SK	SL
<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>

[MORE INFO](#)

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;


Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

## ANNEX I

### ESSENTIAL REQUIREMENTS

8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.


**Enterprise and Industry**


Important legal notice

English ▾

EUROPA > European Commission > Enterprise & Industry > Policy Areas > Single Market > New Approach > Harmonised standards
 

Contact | Search

[What's new?](#) | [Site map](#) | [Index](#) | [Information](#) | [FAQ](#) | [About this site](#)



## HARMONISED STANDARDS

New Approach

Overview

Harmonised standards

Introduction

References of harmonised standards

List of directives and subjects

Legislation

Access to EU legislation

Other information

[News and updates](#)  
[Archive](#)  
[Reference documents](#)

Useful links

[Related websites](#)  
[European Standards Organisations](#)

### INTRODUCTION


The "New Approach", defined in a Council Resolution of May 1985, represents an innovative way of technical harmonisation. It introduces, among other things, a clear separation of responsibilities between the EC legislator and the European standards bodies CEN, CENELEC and ETSI in the legal framework allowing for the free movement of goods.

- EC directives define the "essential requirements", e.g., protection of health and safety, that goods must meet when they are placed on the market.
- The European standards bodies have the task of drawing up the corresponding technical specifications meeting the essential requirements of the directives, compliance with which will provide a presumption of conformity with the essential requirements. Such specifications are referred to as "harmonised standards".

[More ...](#)

**Harmonised standards**

"Harmonised standards" are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties.



New on this website

World Standards Day 14 October 2005

['International Cooperation in Standardisation' Conference](#)

NEW

News and updates

[Review of changes and additions to this site](#)

New references

[Lifts](#)

NEW

OJ C192 of 2005-08-02

[Machinery](#)

NEW

OJ C192 of 2005-08-06

[Toys](#)

NEW

OJ C188 of 2005-08-02

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>

Adres  <http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>   Ga naar [Koppelingen](#)

 **Enterprise and Industry** [Important legal notice](#) [English](#) 

[EUROPA](#) > [European Commission](#) > [Enterprise & Industry](#) > [Policy Areas](#) > [Single Market](#) > [New Approach](#) > [Harmonised standards](#) > [List of directives & subjects](#) > [Medical devices](#) [Contact](#) | [Search](#)

[What's new?](#) | [Site map](#) | [Index](#) | [Information](#) | [FAQ](#) | [About this site](#)

 **HARMONISED STANDARDS**

[New Approach Overview](#)

[Harmonised standards Introduction](#)

**MEDICAL DEVICES**

[Directive 93/42/EEC concerning medical devices](#)



## In Belgium

- 50 % of steam sterilizers > 10 years old
- 33 % are validated annually

1. History of sterilization
2. The role of the associations
  - National
  - European
  - Global
3. The Medical Device Directive
4. A survey

1. Are the European norms known by the sterilization departments in your country?

Total: 10 of 13 yes

EU: 7 of 8 yes

Non EU: 3 of 5 yes

## 2. Are the European norms being applied?

Total:	5 of 13 yes
	5 of 13 +/-
EU:	4 of 8 yes
Non EU:	1 of 5 yes

3. Does the CSSD in your country generally meet the 'state of the art'?

Total:	5 of 13 yes
	4 of 13 +/-
EU:	4 of 8 yes
	3 of 8 +/-
Non EU:	1 of 5 yes

## 4. What can be improved?

- Education of the personnel: 8 of 13 !!!
- Inspections & validation
- Design & equipment

## 5. Are there national norms for the CSSD?

Total:	9 of 13 yes
--------	-------------

EU:	5 of 8 yes
-----	------------

Non EU:	4 of 5 yes
---------	------------

6. Is there still reuse of single use medical devices?

Total:	10 of 13 yes
--------	--------------

EU:	5 of 8 yes
-----	------------

Non EU:	5 of 5 yes
---------	------------

7. Is there an education for CSSD personnel?

- Technicians? 9 of 13 yes (EU: 6 / 8 , non EU: 3 / 5)
- Teamleaders? 9 of 13 yes (EU: 6 / 8 , non EU: 3 / 5)
- Managers? 10 of 13 yes (EU: 7 / 8 , non EU: 3 / 5)

## VSZ enquête CSA

Opleiding	intern	Intern gem aantal uren	VSZ basis	VSZ verdieping	Andere
Hoofd CSA	18,6%	15,75 uur	27,9%	25,60%	34,9%
Teamchef	9,3%	10 uur	10,84%	6,44%	9,30%

### •Hoofd CSA

- Ongeveer 60% heeft een opleiding gevolgd
- Slecht een beperkt aantal volgt een jaarlijkse interne opleiding gedurende een zeer beperkt aantal uren
  - 4 ⇔ 30 uur

### •Teamchefs

- Slechts een beperkt aantal heeft een externe opleiding gevolgd
- Interne opleiding is een uitzondering
  - 4 ⇔ 24 uur

## VSZ enquête CSA

Opleiding	intern	Intern gem aantal uren	VSZ basis	VSZ verdieping	Andere
Medewerkers	27,9%	10,8 uur	33,3%	0,35%	1,26%
Logistiek ass.	16 %	9 uur	20%		2,33%

### •Medewerkers

- Ongeveer 60% heeft een opleiding gevolgd
- Slecht in  $\frac{1}{4}$  van de CSA's wordt een jaarlijkse interne opleiding voor medewerkers gedurende een zeer beperkt aantal uren georganiseerd
  - 2 ⇔ 25 uur
- 2 op 3 CSA medewerkers heeft geen basiscursus gevolgd
- In 32,5 % van de CSA heeft geen enkele medewerker een basiscursus gevolgd
- 0,5 % heeft een verdiepingscursus gevolgd

### •Logistiek assistenten

- 20 % heeft een basiscursus gevolgd
- In de CSA met logistiek assistenten wordt in slechts 16% een interne

1. History of sterilization
2. The role of the associations
  - National
  - European
  - Global
3. The Medical Device Directive
4. A survey
5. Examples

# Germany



Germany



WFHSS



# Belgium



# Belgium



Latvia



# Latvia



Latvia



Bulgaria



# Bulgaria



# Bulgaria



Turkey



Turkey



Turkey



# Turkey



1. History of sterilization
2. The role of the associations
  - National
  - European
  - Global
3. The Medical Device Directive
4. A survey
5. Examples
6. Putting theory into practice

Keep it simple !





WFHSS



WFHSS



---

# Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007

---

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD;  
Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory  
Committee

**Acknowledgement:** The authors and HICPAC gratefully acknowledge Dr. Larry Straustaugh  
for his many contributions and valued guidance in the preparation of this guideline.

*Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection  
Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing  
Transmission of Infectious Agents in Healthcare Settings, June 2007*  
<http://www.cdc.gov/hicpac/2007guideline/isolation2007.pdf>

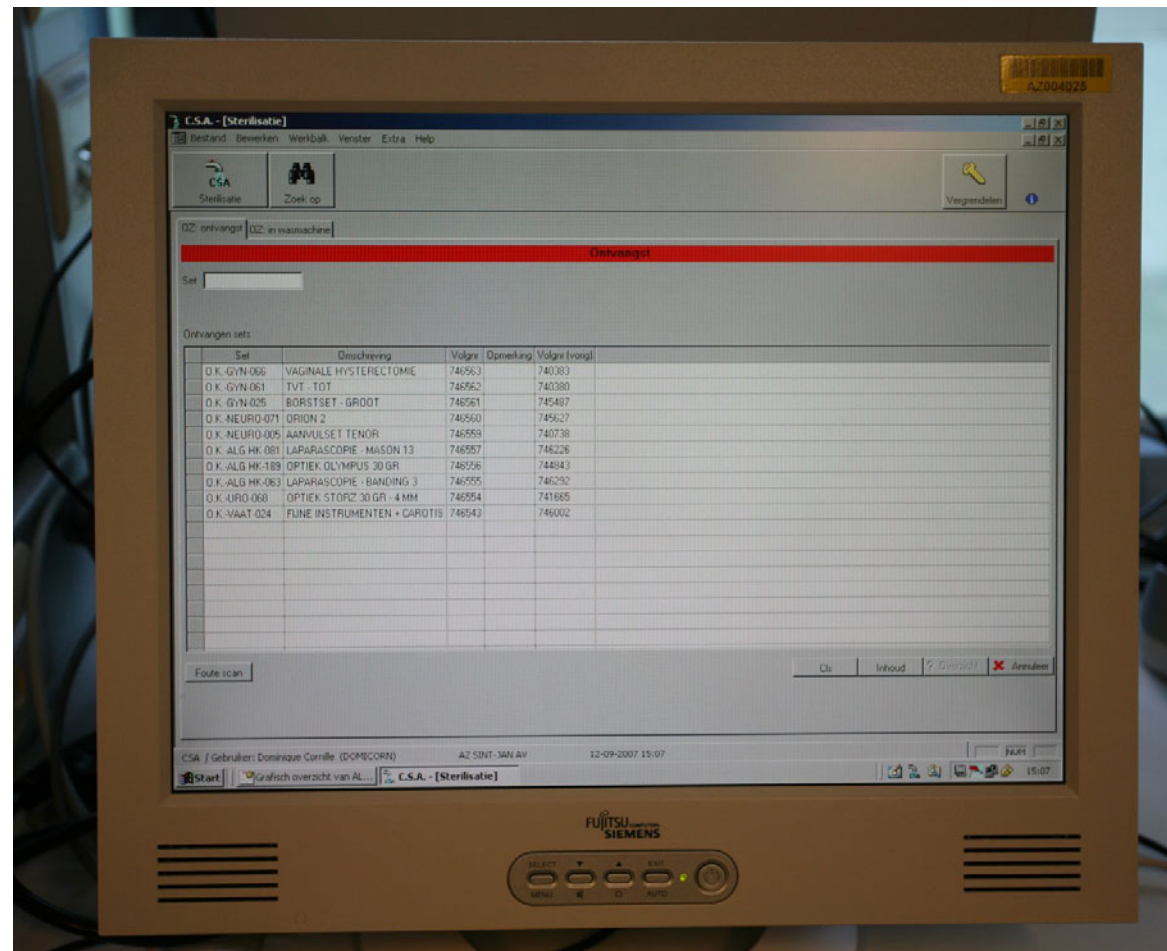


WFHSS





— WFHSS —

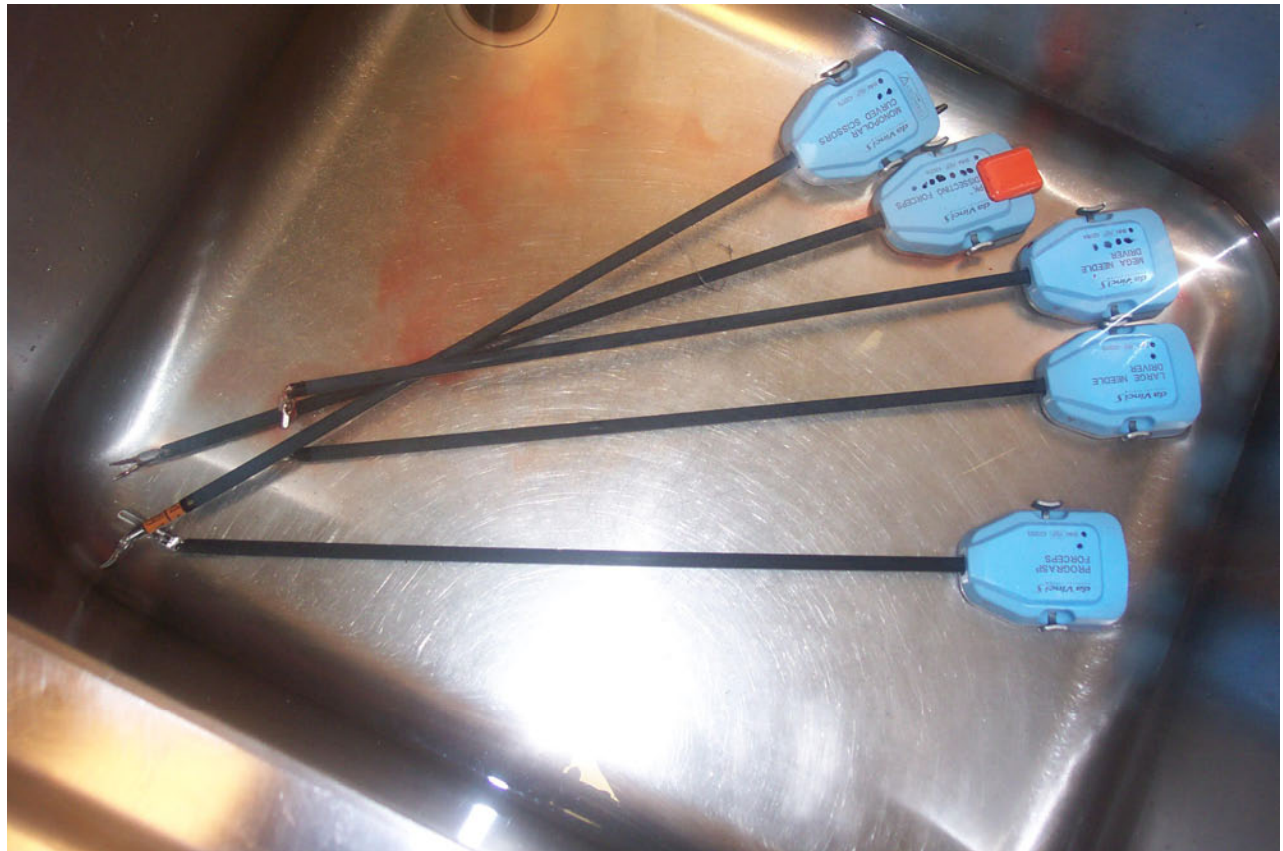


# WFHSS

**da Vinci** HD  
SURGICAL SYSTEM



Experience Surgery in  
High Definition **3D HD**



Ultrasonic unit

Rinsing



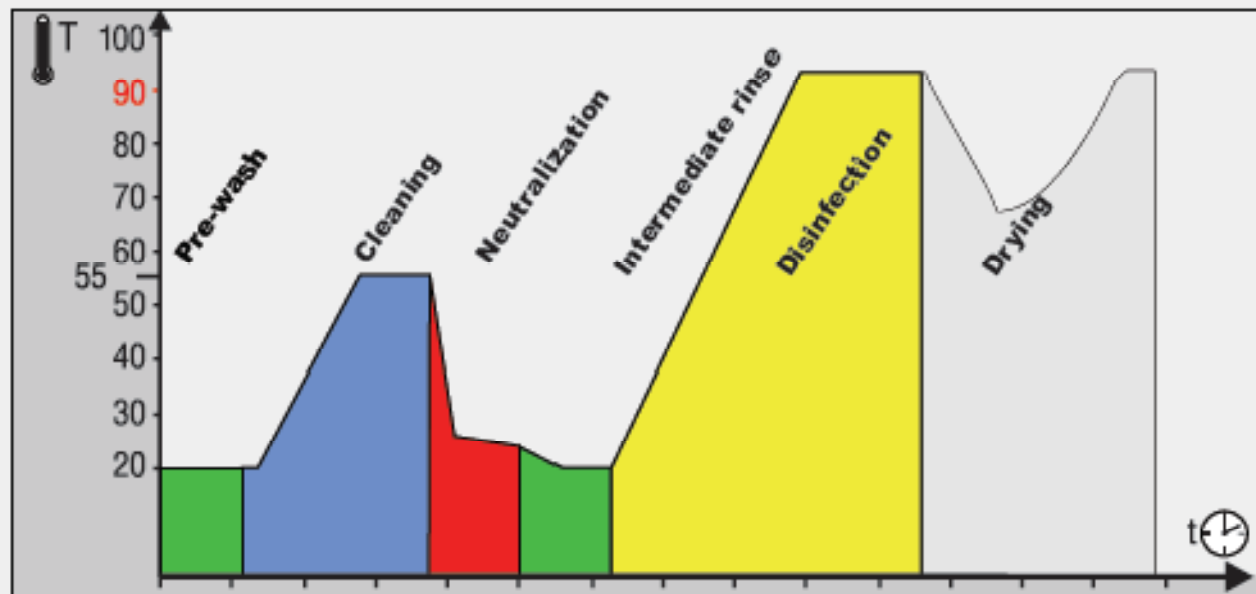


WFHSS

WFHSS



## Cleaning and thermal disinfection process



Dr. Michels

RKI recommendations:

- Alkaline detergents
- Disinfection 5 min 90°C
- Sterilisation: 5' 134°C

## Disinfection parameters:

- $A_0 = 600 \text{ sec}$  ( $80^\circ\text{C}$  ,  $Z = 10^\circ\text{C}$ ): uncritical
- $A_0 = 3000 \text{ sec}$  : semi-critical & critical

U. Rosenberg

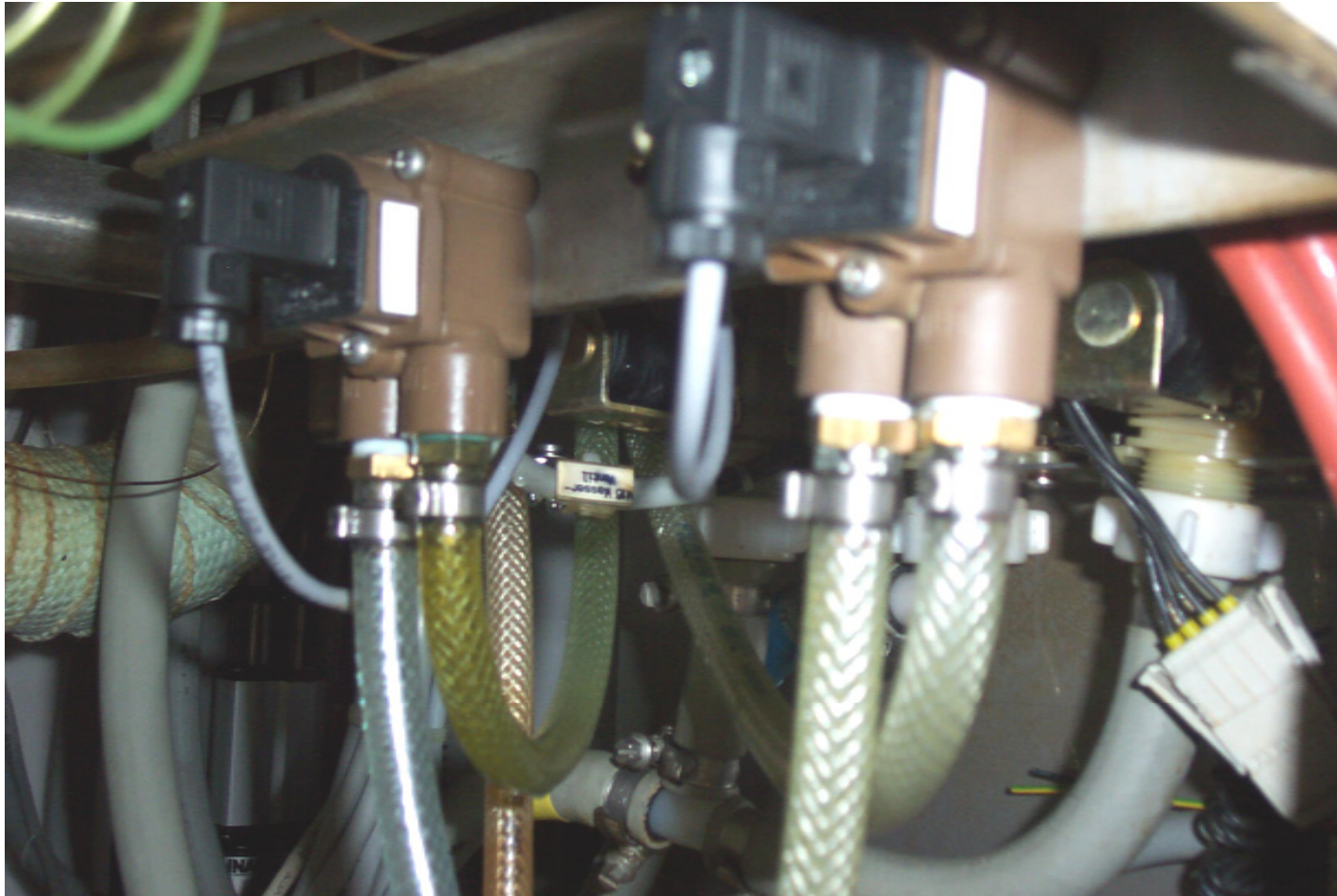
### Thermal Disinfection – The $A_0$ Concept and the Biological Background

Thermische Desinfektion – das  $A_0$ -Konzept und der biologische Hintergrund

This paper focuses on parametric control of thermal disinfection and on its relationship to the biology underlying the killing/inactivation of microorganisms through moist heat. The disinfection parameters ( $A_0$  values) as recommended in the standard, or their interpretation, are critically reviewed. It would probably be advisable to replace the overkill approach, which is especially prevalent in German-speaking countries, by improved cleaning. (Zentr Steril 2003; 11 (2): 115–120.)

thermische Desinfektion, parametrische Freigabe,  $A_0$ -Wert, thermal disinfection, parametric release,  $A_0$  value

WFHSS





WFHSS

WFHSS



WFHSS





# WFHSS



WFHSS



WFHSS



WFHSS



WFHSS





WFHSS



WFHSS









WFHSS











WFHSS

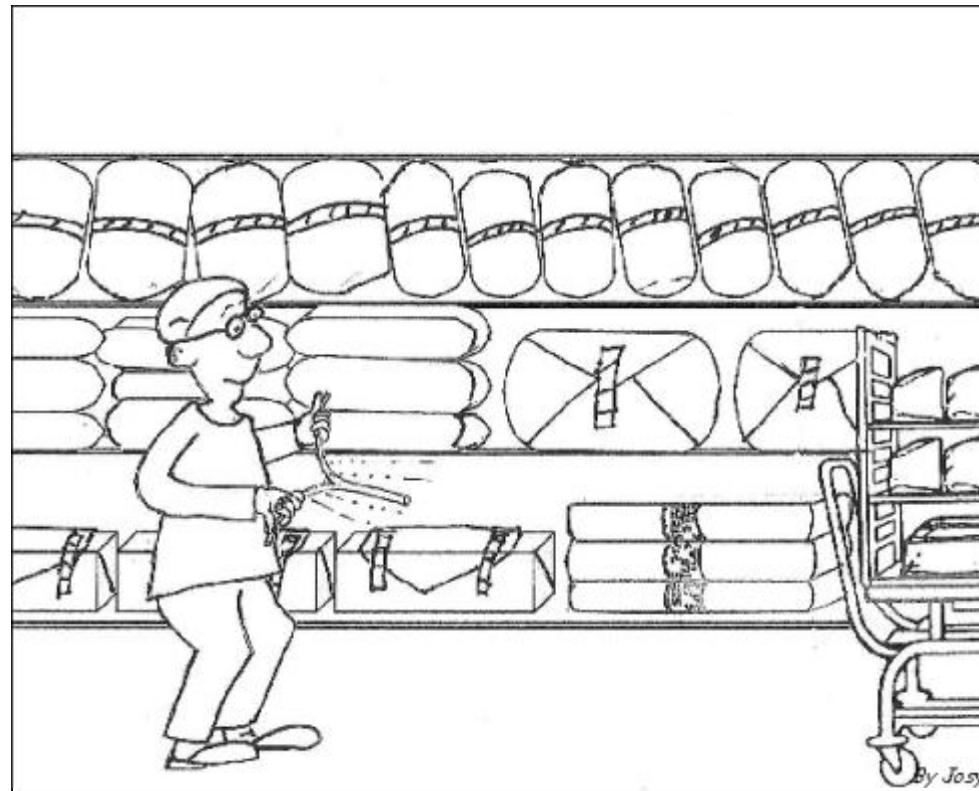


WFHSS



WFHSS





WFHSS



WFHSS



WFHSS







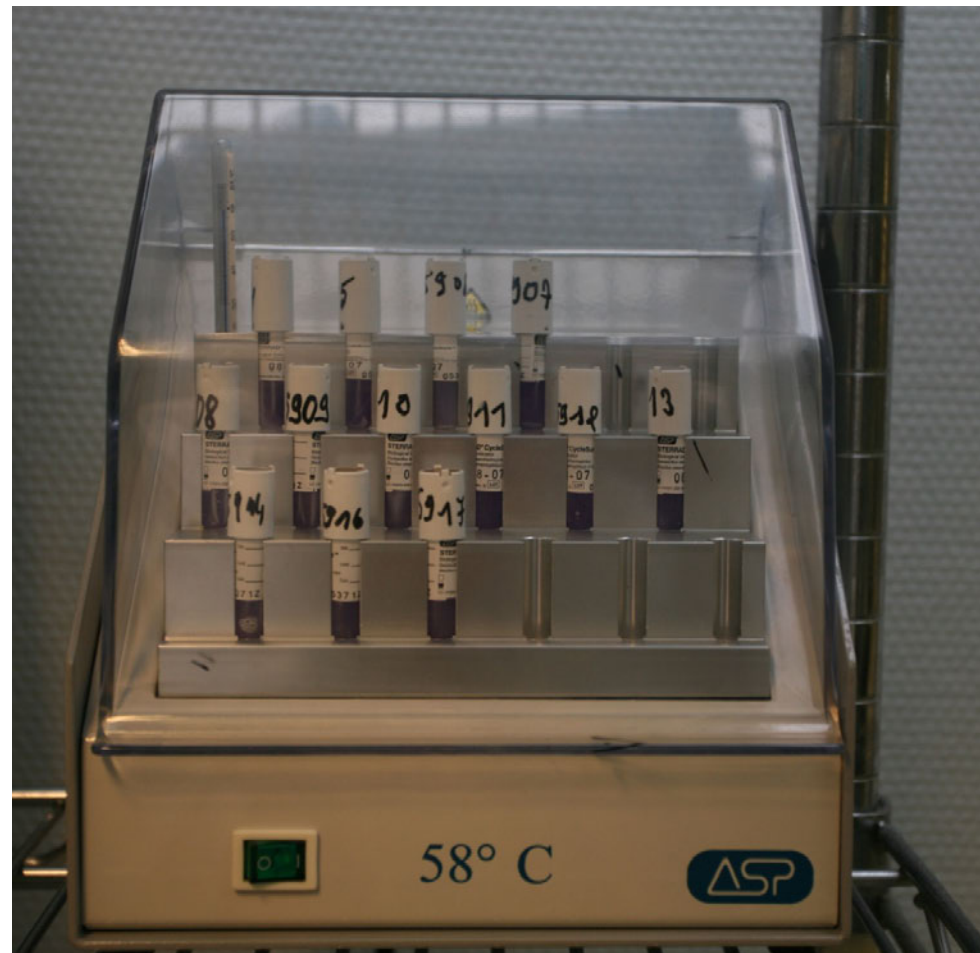
WFHSS

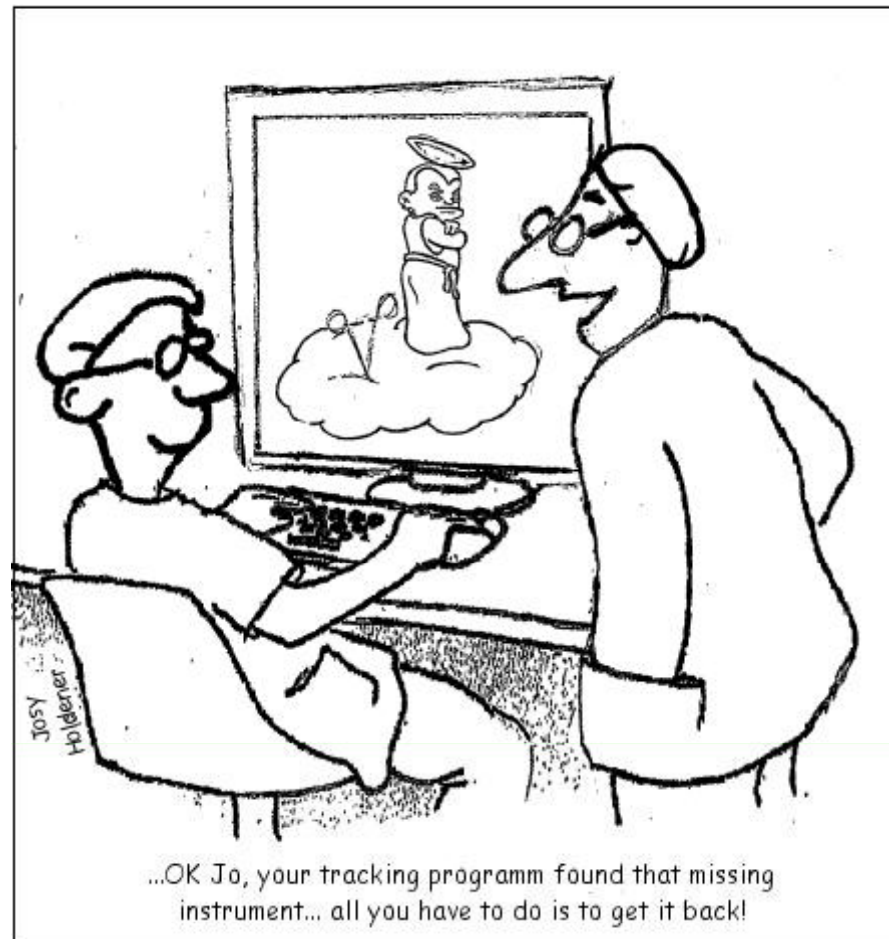


WFHSS



WFHSS





## Conclusion

- Sterilization in Europe is not different from sterilization in the rest of the world
- The road to the goal is or becomes the goal itself

THANK YOU!

WFHSS