Welcome WFHSS

OMAN November 2nd 2006
Middle East WFHSS Workshop
FiberSolutions

Ahlstrom
TIM GALEKOP
Director of Global Business Development
Medical Fabrics

Convenor CEN TC 102 WG 4
Expert ISO TC 198 WG 7
Expert CEN TC 205 WG 14
Of June 14 1993
Concerning Medical Devices
Patient’s Safety
and
Staff’s Safety
CEN TC 102 WG 4

Established May 3rd 1988
EN 868-1 ratified / published February 1997
EN 868 2 – 10 ratified / published June 1999
CEN - TC 102 - WG4
Packaging Materials And Systems For Medical Devices Which Are To Be Sterilized

EN 868-1 Part 1 : General requirements and test methods

Requirements and test methods.

EN 868-3 Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels.
Requirements and test methods.

EN 868-4 Paper bags.
Requirements and test methods.

EN 868-5 Heat and self-seal able pouches and reels of paper and plastic film construction.
Requirements and test methods.
## CEN - TC 102 - WG4
Packaging Materials And Systems For Medical Devices Which Are To Be Sterilized

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 868-6</td>
<td>Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods.</td>
</tr>
<tr>
<td>EN 868-7</td>
<td>Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or radiation. Requirements and test methods.</td>
</tr>
<tr>
<td>EN 868-8</td>
<td>Re-usable sterilization containers for steam sterilizers confirming to EN 285. Requirements and test methods.</td>
</tr>
</tbody>
</table>
CEN - TC 102 - WG4
Packaging Materials And Systems For Medical Devices Which Are To Be Sterilized

EN 868-9
Nonwoven uncoated materials of high density polyethylene fibres (Nonwoven HDPE) for the use in the manufacture of pouches, reels and lids. Requirements and test methods.

EN 868-10
Adhesive coated Nonwoven materials for the manufacture of high density polyethylene fibres (HDPE) for the use in the manufacture of heat sealable pouches, reels and lids. Requirements and test methods.
Bacterial barrier

Barrier = a tortuous path
INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

ISO TC 198 WG 7

ISO 11607
PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES

Part 1: Requirements for materials, sterile barrier systems and packaging systems
PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES

Part 2: Validation requirements for forming, sealing and assembly processes
This ISO standard is applicable to industry, healthcare facilities, and wherever medical devices are sterilized.
<table>
<thead>
<tr>
<th>Part 1</th>
<th>Part 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Introduction</td>
</tr>
<tr>
<td>Scope</td>
<td>Scope</td>
</tr>
<tr>
<td>Normative References</td>
<td>Normative References</td>
</tr>
<tr>
<td>Terms and Definitions</td>
<td>Terms and Definitions</td>
</tr>
<tr>
<td>General Requirements</td>
<td>General Requirements</td>
</tr>
<tr>
<td>Documentation</td>
<td>Documentation</td>
</tr>
<tr>
<td>General</td>
<td>General</td>
</tr>
<tr>
<td>Packaging Materials</td>
<td>Packaging Process</td>
</tr>
<tr>
<td>Final Package</td>
<td>Packaging Assembly</td>
</tr>
<tr>
<td>Bibliography</td>
<td>Bibliography</td>
</tr>
<tr>
<td>Appendices</td>
<td>Appendices</td>
</tr>
</tbody>
</table>


FiberSolutions
“Sterile Barrier System”

The minimum packaging configuration that maintains sterility of the package contents until aseptic presentation at the point of use
Protective Packaging

The packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.
Packaging System

The combination of the Sterile Barrier System and the Protective Packaging
GLOBAL PERSPECTIVE ON ISO 11607 & INTERGRATION OF EN 868 - 1

- It's (not) too late to lock the stable door after the horse has bolted
- First Medical Devices Law published 1970 in The Netherlands.
- Proof your claim.
WHAT WILL CHANGE WITH THE INTRODUCTION OF ISO/EN 11607?

• End of the ostrich politics!
• Stop confusion.
• We speak globally the same language hospitals & Industry.
• Results from the same test methods.
WHAT WILL CHANGE WITH THE INTRODUCTION OF ISO/EN 11607?

• Separate the wheat from the chaff!
• Two documents.
• Improve quality.
• Development new and improved SBS.
WHAT WILL CHANGE WITH THE INTRODUCTION OF ISO/EN 11607?

• ONE RULE FOR Industry / Hospitals Dentist / Doctors / Private institutions
• We speak globally the same language
• EN 868 – 2 / 10
• Safety Patient and Staff.
CURRENT SITUATION

ISO 11607-1 and ISO 11607-2 have been published as European Standards without any modification. Both standards, i.e. EN ISO 11607-1 and -2, have to be implemented by all CEN members (see list in the European foreword) by October 2006. EN ISO 11607-1 replaces EN 868-1. However, EN 868-1 has to be withdrawn by April 2007 at the LATEST. This means that manufacturers (do not have to but) CAN refer to EN 868-1 until April 2007.

Instructions for use of ISO / EN 11607

Another important point is that EN 868-1 is referenced in the Official Journal of the European Commission. This is still open for EN ISO 11607-1 and -2;

EN 868 2 and subsequent parts are under revision.

Sterile field ?

FiberSolutions
Let us not forget we are talking about the safety of the PATIENT and staff.
EUROPEAN FORUM FOR HOSPITAL STERILE SUPPLY
HTTP://WWW.WFHSS.COM
HTTP://WWW.EFHSS.COM
DO WE HAVE BLINKERS ON?
Thank you and,
Don’t become the patient.