Sustainability, Environment and Packaging in Health Care

Åsa Westling & Jenny Flach 2024 –10-18

Webinar: Bærekraft i anestesi- og intensivbehandling, Standard Norge

Agenda

Mölnlycke Green mindset

Net zero company
Science based targets
Sustainability achievements and targets

Packaging standards

Why are they important
Which standards are we using

Mölnlycke at a glance

World-leading MedTech company that specializes in sustainable solutions for wound care and surgical procedures.

Global HQ
in Gothenburg, Sweden

8,427
employees worldwide

99%
owned by Investor AB

100
countries where Mölnlycke is present

Revolutionise care
for people and planet

Our Business Areas

Wound Care

Operating Room Solutions

Gloves

Antiseptics

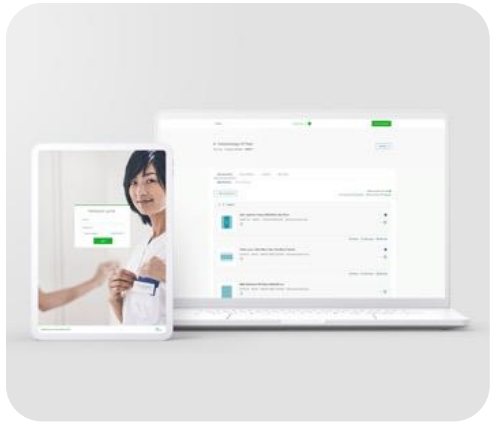
Operating Room Solutions and Products

BARRIER® Drapes
and Staff clothing

EasyWarm
Patient Warming

Surgical
instruments

ProcedurePak®
customised trays



Digital
services

Sterile products and
non-sterile products

Sustainability Roadmap

PLATINUM Top 1%
ecovadis
Sustainability Rating
JUL 2024

In relation to UN Sustainable Development Goals

Green mindset

→ We are constantly innovating to offer our customers the most sustainable solutions, while not compromising on safety and quality of our products

Reduce our Environmental and Climate impact

Mölnlycke committed to Science Based Targets Initiative – SBTi

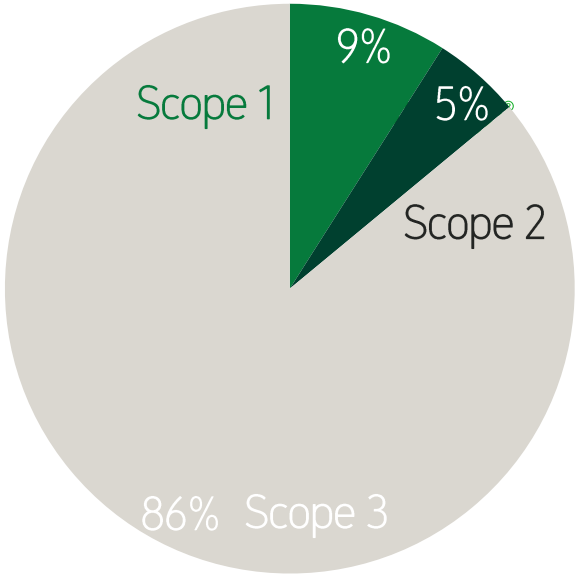
→ Science-based targets
- provide a pathway for companies to reduce greenhouse gas (GHG) emissions,
- set reductions targets in line with what is needed to keep global heating below catastrophic levels, 1,5 degree C
- reach net-zero by 2050 at latest

→ Mölnlycke near-term GHG reduction targets validated by SBTi

SCIENCE BASED TARGETS

DRIVING AMBITIOUS CORPORATE CLIMATE ACTION

Green mindset



Reduce our Environmental and Climate impact – Targets

	GHG emissions (Science Based Targets, SBTi)			Resource efficiency	Sustainable portfolio
Targets	Net Zero 2050 Scope 1, 2, 3	50% reduction 2030 Scope 1, 2 *	20% reduction 2028 Scope 3 *	95% recyclable packaging 2030	Assess sustainability profile of our product portfolio by 2025
2023 achievements	20%	28%	18%	90%	30% Mölnlycke products Life Cycle Assessment

** Scope 1: Emissions from own facilities, Scope 2: Emissions from purchased energy, Scope 3: all emissions from upstream and downstream processes*
** Reduction in absolute GHG emissions vs 2021 baseline*

Sustainability examples from products

- → Biobased raw material, ISCC-certified in several products
  - BARRIER ISCC Primary Plus surgical gown
    14% lower CO_2e emissions*.
- → Reduced weight with preserved product function
  - BARRIER ISCC Mayo Stand Cover - weight reduction exceeding 20%*
- → Moving from single packed items to Mölnlycke® ProcedurePak® trays can reduce surgical packaging waste by up to 90%
- → FSC certified (sustainable forestry) Paper/cardboard packaging

** Mölnlycke Annual report 2023*

Packaging for Operating Room Solutions

- Three-layer principle, preserve function and sterility

Or:

Primary packaging
/ Sterile barrier

Secondary packaging
Retail box

Tertiary packaging
Transport box

Mölnlycke Packaging sustainability targets

- → Reduce amount of packaging material, without compromising functionality of the packaging
- → > 95% of our packaging recyclable by 2030
- → > 80% of our packaging consist of renewable and/or recycled (PCR) material by 2030
- → > 80% of our paper/cardboard packaging to be FSC/PEFC certified (sustainable forestry) by 2030
- → Work with suppliers and external partners to improve packaging solutions (incl input to sustainability assessment and Life Cycle Assessment)

Mölnlycke packaging sustainability targets are aligned with the new EU Packaging and Packaging Waste Regulation (PPWR).
PCR: Post consumer recycled, FSC: Forrest Stewardship Council, PEFC: Programme for the Endorsement of Forest Certification.

Packaging standards

Why are standards important

Which standards are we using

Why are standards important

- Ensures compliance with regulations
- Provides a common language and expectations
- Ensures product quality and patient safety
- Improves the usability of medical devices by ensuring that instructions, labeling, and handling processes are clear and consistent.
- Less confusion
- Peace of mind

We have an infrastructure

- Quality Management System
  Policys, procedures, work instructions
- Documentation system
- Declaration of conformity DoC (CE marking)
- Third party Audits to ensure compliance
- Staff training and internal certification (regularly)

Which standards are we using?

Design Input	Design Output	Design Verification	Design Validation	Design Transfer
User needs **Functionality** **Standards** **Sustainability** **Manufacturing**	Develop design	Test design requirements	User need testing Manufacturing Process validation	Process testing
Design requirements	Design specifications	Lab testing Supplier statements*	Usability studies Clinical data Process validation	

We have standards in all phases of development

* Incl REACH statements and specific chemical statements

Design Input → Design Output → Design Verification → Design Validation → Design Transfer

EN ISO 14971 Medical devices
Application of risk management to medical devices

ISO 11607 Packaging for Terminally Sterilized Medical Devices.
Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems.

Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes.

ASTM D4169 (from ISO 11607)
Standard Practice for Performance Testing of Shipping Containers and Systems.

ISO 10993-1 Biological Evaluation

EN 13430 Packaging - Requirements for packaging recoverable by material recycling

EN ISO 14971

Medical devices - Application of risk management to medical devices

A framework for managing risks associated with medical devices throughout their entire lifecycle.

1.Risk Management Process
2.Perform Risk Analysis
3.Perform Risk Evaluation
4.Perform Risk Control
5.Perform Residual Risk Evaluation
6.Perfom Risk Management Review
7. Review and update Production and Post-Production Information

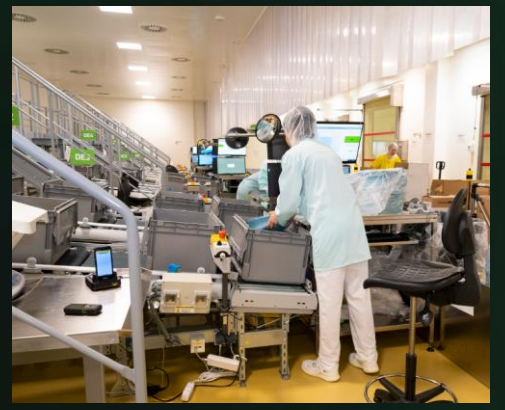
ISO 11607

Packaging for Terminally Sterilized Medical Devices.

Input to Material selection
Sterilization
Compatibility with device
Labelling and worse case testing
Integrity after distribution
Continous quality during production

Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems.

Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes.



ASTM D4169 (from ISO 11607)

Standard Practice for Performance Testing of Shipping Containers and Systems.

Packaging Systems: Should be designed to protect the sterile barrier system and the device during transportation. Maintain integrity

ASTM D4169 defined as the method best describing our worst case Simulation of supply chain routes ,
Distribution cycle (DC-1 DC-2 DC-13)

Shock Vibration Compression Environmental hazards (temperature pressure)

ISO 10993-1

Biological Evaluation

Risk Management Process: Evaluation and testing must be part of a structured risk management process.

Material Characterization: Identify and characterize materials used in packaging to assess potential biological risks.

Biological Evaluation Plan
Perform biocompatibility testing or provide a rationale for why certain tests are not needed based on existing data

- Cytotoxicity
- Sensitization
- Systemic toxicity
- etc

EN 13430

Requirements for packaging recoverable by material recycling

Material Composition: Packaging must be made from materials that can be effectively separated and recycled.

Design for Recycling: The design of the packaging should facilitate easy recycling.

Recycling Processes: The packaging must be compatible with existing recycling processes

Plastic: RecyClass (A-B), Cyclos-HTP Institute, CEFLEX

Paper Cepi: (Confederation of European Paper Industries)

Design Input → Design Output → Design Verification → Design Validation → Design Transfer

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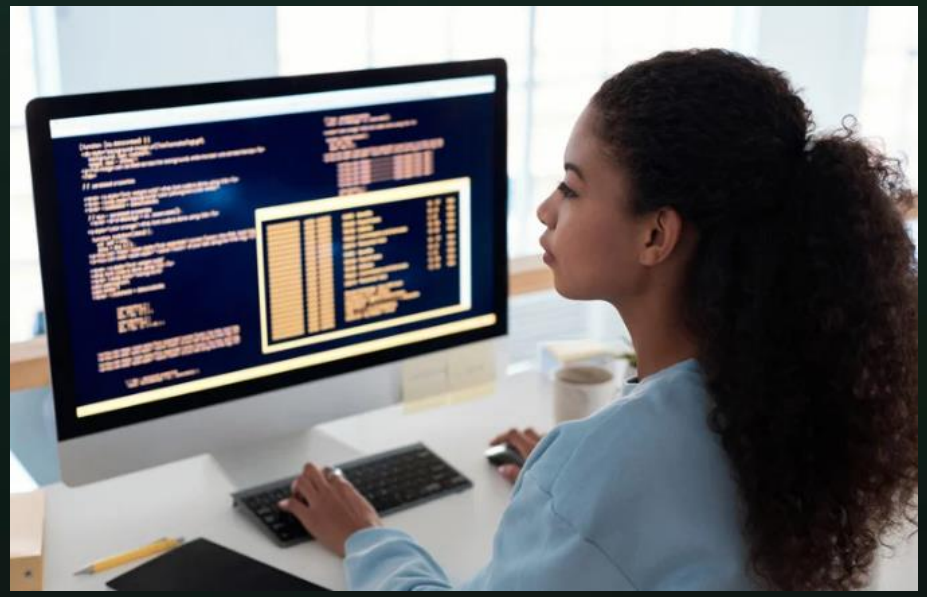
Design Verification

Standarized testing in climate controlled laboratories
Trained staff assigned for specific methods
Validated equipment



Design Input → Design Output → Design Verification → Design Validation → Design Transfer

Flex durabiliy (Mölnlycke T-2111)
ASTM F392/F392M – 11

Seal strenght (Mölnlycke T-232)
SS-EN ISO 9073-4 : 1997

Puncture resistance (Mölnlycke T-2108)
ASTM F1306 – 16

and many more...

Challenges

Time

Space

Lacking instructions

Many variants of packaging

Poorly designed packaging difficult to open

To many layers of packaging

Sorting confusion

PPWR

Packaging and packaging waste regulation

Time

Space

Lacking instructions

Many variants of packaging

Poorly designed packaging difficult to open

To many layers of packaging

Sorting confusion

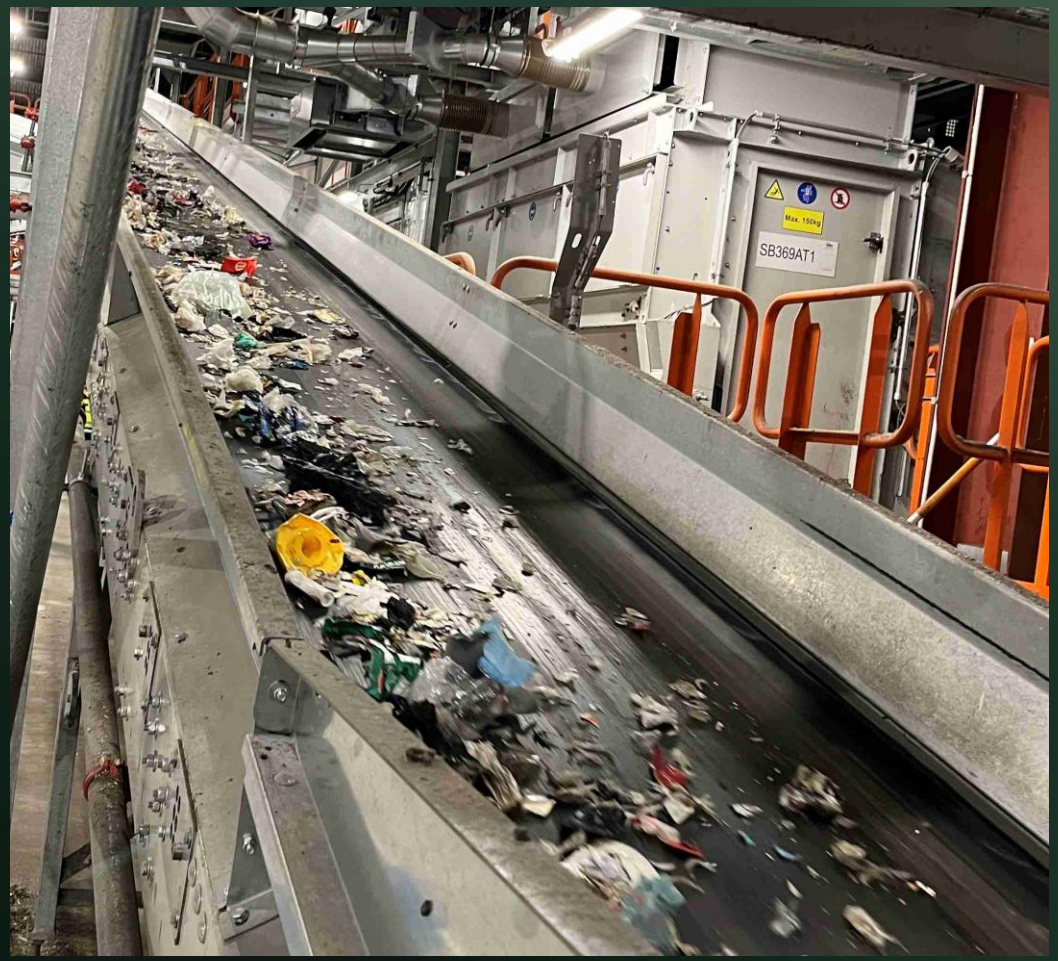
Standardization

Simplifies for all

Stakeholders

Reduce amount

of choices



Summary

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Thank You !