



Sterile Barrier Association

2024

# Annual Report

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# Contents

2	Glossary of terms and acronyms
3	Editorial
3	Letter from the Director General
3	2024 Board of Directors
4	Overview of the Year - Membership
4	2024 SBA Member Companies
5	2024 Update on Committees
7	Annual Conferences
8	Communications
9	Development and Growth
10	Conclusions and Outlook for 2025



## Glossary of terms and acronyms

**AI**  
Artificial Intelligence

**ASTM**  
Formerly known as American Society for Testing and Materials, a standards organization that develops and publishes voluntary consensus technical international standards

**CSR**  
Corporate Social Responsibility

**CSRD**  
Corporate Sustainability Reporting Directive

**DG**  
Director General

**MDD**  
Medical Device Directive

**MDM**  
Medical Device Manufacturer

**MDR**  
Medical Device Regulation

**PPWR**  
Packaging and Packaging Waste Directive

**SBA**  
Sterile Barrier Association

**SBS**  
Sterile Barrier Systems, sterilized medical packaging that keeps a device safe and sterile until the point of use

**WFHSS**  
World Federation for Hospital Sterilization Sciences

# Sterile Barrier Association (SBA) Annual Report 2024

I am very proud to introduce this first SBA annual report. It's always a good idea to report, both publicly and for members, about the work and progress of the past year. This shows the value that is brought by the association to its members, to the industry and to patients. Since 2021, the SBA has chosen to organize its work through 4 committees, aligning with a renewed vision and service level towards its members. You will see that, thanks to an increased involvement of many of our members, some very significant work has been achieved, which we can all be proud of.

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members, some very significant work has been achieved, that we can all be proud of.

The organization and the communication of the association has also tremendously progressed thanks to the great work of our Director General and her team.

I would like to thank and congratulate all the members who have been working in the committees and working groups, and encourage everybody to do the same, in order that the association can bring even more value in the future.

Thibaut Hyvernât, Chair of the SBA



## 2024 Board of Directors

The SBA is managed by a Board of Directors, comprising of up to eight people, drawn from the membership plus the Director General as an ex-officio.

The SBA Board of Directors for 2024 includes distinguished leaders from various companies within the sterile barrier industry:



**Chair: Thibaut Hyvernât**, Sterimed, France (first row right)

**Director General: Nina Tillaëus**, Tillacon, Finland (first row left)

Directors (standing, from left to right):

**Mayte Rojas**, Bolsaplast, Spain

**Fritz van Gastel**, Nelipak, the Netherlands

**Thierry Wagner**, DuPont, Luxemburg

**Christian Wolf**, hawo, Germany

**Tanja Venäläinen**, Wipak, Finland

**Missing from the photo:**

**Ralph Basile**, Healthmark, USA

**Jonathan Andrews**, Pelta Medical Papers, UK, resigned in Spring 2024

**Dhuanne Dodrill**, Paxxus, USA elected as a new Director in April 2024

## Letter from the Director General

This SBA Annual Report 2024 is the first official review of the activities and achievements of the Sterile Barrier Association and a starting point for the association's annual reporting. From now on the SBA will publish an Annual Report every year, that documents the work that the association has been involved in during the previous 12 months.

The SBA is a European trade association for the producers of sterile barrier systems. This report summarizes the strategic goals of the SBA and provides an overview of our association's governance, membership status, and key initiatives, with a focus on the vital role we play in promoting patient safety through the correct use of medical packaging solutions. It also describes our key activities in the year 2024.

I encourage you to read through the pages of this report and join us in celebrating our achievements in 2024.

Yours sincerely

Nina Tillaëus  
Director General of the SBA



# Overview of the year Membership

## Mission

The primary objective of the SBA is to promote the correct use of Sterile Barrier Systems to ensure patient safety. This is achieved through:

- **Guidance and Education:** Providing best practices, handling techniques, and regulatory updates.
- **Advocacy and Standardization:** Engaging with European and international regulatory bodies to influence legislation and promote the interests of the sterile barrier industry.
- **Sustainability Initiatives:** Encouraging environmentally and socially responsible practices within the healthcare packaging sector.

## 2024 SBA Member Companies

The SBA's membership comprises leading organizations in the sterile barrier industry, including Ahlstrom, All-Flex, Amaco, Amcor, Billerud, Bolsaplast, Coldenhove, Coveris, DuPont, ECS, Encaplast, Halyard, hawo, Healthmark, Klöckner Pentaplast, La-Co Tempil, M-Pack, Nelipak, Oliver, Paxxus, Pelta Medical papers, Sigma, Sterifast, Sterimed, Steripack, Südpack, Tagleef, TeknipleX, VP, Wipak, 4A Medical.

At the end of 2024 the SBA also gained two new members when Indafor (part of Mativ) joined as its own company and Selenis was also approved as a new member.

These companies contribute to and benefit from the SBA's collective expertise, research, and advocacy efforts aimed at enhancing patient safety and compliance with global regulations.



## Benefits of being a member

### Networking

Meet experts and practitioners in medical packaging. Exchange ideas, support the industry, and have an influence.

### Industry information

Access information, resources, educational content, and the latest developments in sterile barrier systems.

### Conferences

Attend bi-annual conferences with external expert speakers, covering technical, legislation, environmental, and medical technology topics.

### Reputation

Grow your organisation's network of industry peers, and boost its reputation.

# 2024 update on Committees

The Sterile Barrier Association has established four committees for our defined work streams: Education, Sustainability, Regulatory and Market Statistics.

The SBA's work is driven by these four key committees, each focusing on critical areas within the sterile barrier industry:



## Education Committee

**Co-Chairs:** Mayte Rojas (Bolsaplast, Spain) & Pieter van Gool (Südpack, Netherlands)

**Mission:** To educate and promote best practices in the use of Sterile Barrier Systems to foster common understanding to reduce procedural risk and improve patient outcomes.

**2024 Achievements:**

- Created the SBA's own branded image library with medical packaging samples to help explain the correct techniques for different sealing methods, aseptic opening etc.
- Artificial Intelligence (AI) Chatbot for the SBA website to help visitors find information about SBS.



## Regulatory Committee

**Co-Chairs:** Thierry Wagner (DuPont, Luxemburg) & Menno Dufour (Ahlstrom, France)

**Mission:** To support SBA members with the legislation and standardisation of European medical device packaging and engage with various stakeholders to influence and promote the interests of the industry.

**2024 Achievements:**

- Published a MDR Guidance Q&A Document and worked on PPWR-related legislation. Strengthened ties with MedTech Europe and other regulatory bodies.





## Sustainability Committee

**Co-Chairs:** Christophe Simon (Sterimed, France) & Jürgen Wirtz (VP, Germany)

**Mission:** To drive sustainable practices across the healthcare packaging industry.

**2024 Achievements:**

- Addressed the Corporate Sustainability Reporting Directive (CSRD).
- Planned the creation of SBA CSR Guidelines and a hospital waste management questionnaire.
- Created a new Environmental and Social Sustainability page at sterilebarrier.org



## Market Statistics Committee

**Co-Chairs:** Dhuanne Dodrill (Paxxus, USA) & Steven Blacow (Pelta Medical Papers, UK)

**Mission:** To build an accurate market picture and evidence base for the sterile barrier industry that can provide persuasive influence on critical matters for the future.

**2024 Achievements:**

- Collected data from member companies for the 2024 Market Report.
- Shared preliminary results at the Autumn Conference.



## Major achievements

- MDD to MDR transition guidance
- PPWR implementation guidance
- Medical Packaging Market report 2020-2023
- AI chatbot for the website



Our Committees are managed by the SBA Committee Manager, Ms. Hanna-Kaisa Kyyrönen, who ensures that all business is conducted as described in the Code of Practice of the SBA.



*“The SBA plays a vital role in promoting patient safety”*

# Annual Conferences

## Spring Conference, April 2024

The SBA Spring Conference took place in Helsinki, Finland, with around 50 participants from member companies. Key topics discussed included:

- Corporate Social Responsibility (CSR) and the new CSR Directive.
- Regulatory updates, particularly concerning the Medical Device Regulation (MDR) and Packaging and Packaging Waste Regulation (PPWR).
- Educational initiatives focusing on the safe use of SBS.

The conference included interesting guest speakers from the World Federation for Hospital Sterilization Sciences (WFHSS), Medtech Finland, PwC Finland and Bravis Hospital in the Netherlands.

## Autumn Conference, October 2024

The Autumn Conference was held in Bologna, Italy, alongside the ASTM conference, fostering collaboration and networking between the two associations. Highlights included:

- A panel discussion on sustainability and other future challenges relating to the SBS in the eyes of MDMs
- Discussions on sustainability initiatives and how to better integrate them into SBA activities.
- Presentation of initial findings from the 2024 Market Statistics report.
- Continued focus on regulatory challenges and standardization efforts.
- A guest presentation from Kiwa Medical Italy on the topic of “MDR Transition, from a notified body perspective” by Marianna Mastroberto.

The core of the conference this time was a workshop about enhancing cooperation between the SBA and ASTM, with a focus on the opportunities for collaboration and the type of support MDMs would like from the Sterile Barrier Association.



Our next Conference will be held in Copenhagen, Denmark, in May 2025.

# 2024 SBA Communications

## SNAPSHOT

Founded in 1992  
30 Members worldwide  
4 Committees  
2 Annual Conferences

### Social Media

In 2024, the SBA's Social Media Channel in LinkedIn had 130,294 impressions from a total of 3,191 followers. LinkedIn followers grew 27%. The SBA started more active postings with the help of the new Communications Manager, Mr. Peter Cura. At the beginning of the year, the posts were published in English, German, French, Italian and Spanish but to avoid confusion and repetition from the larger number of posts and multiple languages, the decision was made to continue posting in only in English, from now on. The LinkedIn auto-translate function will still enable members to read posts in their own language.

### Website

The official SBA website at sterilebarrier.org had around 11,000 visitors over the past 12 months. A new AI Chatbot was launched by the Education Committee in Autumn 2024 to help site users find answers to their questions about SBS more easily.

### Newsletters and Exhibitions

The SBA also continued publishing the Members Newsletter in 2024. We also attended the Medtech Forum in Austria, Packout in the US and Medica/Compamed in Germany, to promote the important work that we do for Protecting the Patient.



130,294  
impressions

3,191  
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11,000+  
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# A year's overview

# Development and Growth

## Financials

The Sterile Barrier Association's income consists solely of membership fees. In 2024, the SBA had over 30 members.

The association's finances are stable. The SBA is a non-profit organization. All collected fees are used on activities that support the target of the association to enhance patient safety through the correct use of sterile barrier systems.

The annual budget is approved by the member companies in the annual general meeting.

The majority of expenses come from the work of the Committees, other projects that aim to support the mission of the SBA as the expert organization in the industry promoting education on the correct use of SBS, and activities that support the development and growth of the Association. In addition, management fees and general overheads must be covered by the income.

## Collaboration

The SBA collaborates with several other organizations, including ASTM Committee F02 on Primary Barrier Packaging, Medtech Europe, CEN, EORNA (European Operating Room Nurses), SPMC (Sterile Packaging Manufacturers Council), WFHSS, BPF (British Plastic Foundation), and the Finnish Plastic Association.



# Conclusions and Outlook for 2025

The SBA has made significant progress in 2024, particularly in education, regulatory compliance, sustainability, and market research.

## Strategic Priorities for 2025 and Beyond

As we look forward to 2025, our focus will remain on expanding our membership, enhancing our educational resources, and continuing our advocacy for the sterile barrier industry. The upcoming year presents opportunities for further collaboration with organizations such as ASTM & WFHSS as we will continue to strive to ensure the highest standards in patient safety.

We expect the discussion around packaging waste to continue and we will put efforts in supporting our members on their way towards more sustainable healthcare packaging solutions.

This report reflects the key activities and structure of the SBA in 2024, showcasing its dedication to industry leadership and member support. Let me know if there are specific sections you'd like to expand or modify.

Thank you for your interest in our report. Please also share it with your colleagues.

We welcome your questions, comments and feedback. You may contact us at: [director.general@sterilebarrier.org](mailto:director.general@sterilebarrier.org)

## SBA Secretariat

Nina Tillaeus, Director General  
Hanna-Kaisa Kyyrönen, Committee Manager  
Peter Cura, Communications Manager







[sterilebarrier.org](http://sterilebarrier.org)



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