CODAN Packaging

CODAN pvb Critical Care GmbH

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CODAN pvb Critical Care GmbH (CODAN pvb CC) feels responsible for the preservation of the environment and implemented an **Energy Management System (EnMS)** which is certified according to **EN ISO 50001.**

CODAN pvb CC considers it important to combine the interests of business, applicable regulations of medical devices and medical demands with the requirements of environmental and climate protection as far as possible. CODAN pvb CC strives to keep its impact on the environment as low as possible.

For this reason, the company is committed to protecting the environment and systematically reducing all environmental pollution caused by its own activities. The company accepts this responsibility by complying with all applicable laws, guidelines and standards regarding environmental protection in all business areas.

The medical devices produced and placed on the market by CODAN are developed in accordance with the **Council Directive 93/42/EEC (MDD)** and **EN ISO 13485** and comply with **EU 2017/745 (Medical Device Regulation, MDR).**

The environmental requirements for the product and its packaging considering its life cycle are already taken into account during development process (requirement specification). The focus is set on the production and disposal of the product and environmental aspects of used raw materials (REACH, RoHS, conflict minerals etc.).

In accordance with MDR, CODAN pvb CC as manufacturer of medical devices provides the user with information on safe disposal of the product. Likewise, the MDR stipulate that the toxicity/biocompatibility of medical devices shall be assessed and the product shall only be placed on the market in case of a positive benefit/risk ratio.

The following information provides an overview of the measures taken regarding environmental aspects for packaging.

Regulatory background

Regulatory background of packaging for sterile medical devices

CODAN pvb CC is manufacturer of sterile single-use medical devices (class IIa/IIb). It is important to understand that the packaging of sterile medical devices is not only needed to protect the products during storage and transport, but also to maintain their sterility throughout the shelf life (usually 3 years after date of manufacturing). Sterile packaging is regulatorily considered as part of the product. Sterile medical devices from CODAN pvb CC are packed in so-called sterile barrier systems or SBS (primary packaging) packed in cardboard; for small products, additional folding boxes need to be used (secondary/tertiary packaging).

In order to meet the requirements of the MDD and MDR, the packaging configurations of CODAN pvb CC sterile medical devices are designed and validated in accordance with the **EN ISO 11607 series "Packaging for terminally sterilized medical devices".**

EN ISO 11607-1 imposes demanding requirements on the materials. The suppliers of the packaging materials need to confirm compliance to EN ISO 11607-1 and the use of **medical grade substances.** As the manufacturer of sterile barrier systems, we have to verify the material properties like **sterilisation resistance, microbial barrier properties, integrity of sterile barrier system, seal strength, Integrity of the sterile barrier sealing** etc. in the course of the packaging validation processes for the respective packaging systems.

The Packaging materials do not contain substances on the SVHC-candidate list by formulation or do not exceed a concentration of 0.1 % (w/w) specified in Article 33 of Regulation (EC) No 1907/2006, MDD and MDR.

The packaging materials are neither nanomaterials nor are nanomaterials used as constitutional raw materials. In the manufacturing process of the packaging materials, no phthalates are used in the formulation.

Primary packaging

Materials primary packaging:
Sterile barrier systems
CODAN pvb CC uses sterile barrier systems made of thermoformed multilayer films sealed against an upper web made of medical paper or uncoated Tyvek® 2FS™ [2].
For soft film PE/PA/PE polymer or PE polymer with sealing layer is used. The selection of materials used depends on the medical device that is packed. For all sterile products, with the exception of the HG-01 sampling adapter, a monomaterial carrier, the Formpeel®-T [3] film, is used.

This PE material with a thickness of 100 µm makes this film the perfect solution for a wide range of applications and the ideal replacement for standard A-PET or PET-G films. Another benefit of Formpeel®-T [3] is its low shrinkback and good forming properties. With its soft and fibre-free peel, Formpeel®-T [3] is easy to seal and can be perfectly combined with various types of Tyvek® [1]. This combination of PE-based mono film Formpeel®-T [3] and Tyvek® 2FS™ [2] is also ideal for ETO sterilisation.

This packaging solution is characterised by good puncture resistance. The packaged medical products are also easier to recognise thanks to the high transparency of the Formpeel®-T [3] film.

We do not use Polyvinyl Chloride (PVC) materials, meaning that all films are completely PVC-free. In addition, neither styrene-based polymers, nor regenerated cellulose or oxo or biodegradable cellulose are used. To date, no biobased polymers and no aluminum-containing materials are applied.

CODAN pvb CC sterile barrier systems are designed for a friendly user-product interface in accordance with **EN 62366-1** and fitted with tear flaps for the specified peel direction of the sterile packaging to ensure easy opening and aseptic provision of the products.

In order to avoid as much packaging waste as possible and save resources, the thickness of the packaging materials was chosen as minimal as possible. Also CODAN pvb CC uses different sizes of sterile barrier systems. The size of the sterile barrier system is chosen depending on the size and volume of the steril product to avoid waste and save resources without compromising the safety and performance of the product and the sterile barrier system.

Secondary/tertiary packaging

Materials secondary/tertiary packaging: Cardboard
To support sustainable forest management, only **FSC-** (Forest Stewardship Council), **PEFC-** (Programme for the Endorsement of Forest Certification Schemes) **or equivalent certified materials** are used as secondary/tertiary packaging. The certification of the materials is verified by default during qualification process of the materials.

In order to keep the impact on the envirionment as low as possible, white cardboard boxes for sterile devices that contain a small amount of new paper have largely replaced by cardboard boxes made from 100 % recycled paper.

Only where the stability of the cardboard boxes requires it or the cardboard boxes are used as reusable protective

[1] Tyvek® is a registered trademark of DuPont
[2] Tyvek® 2FS™ is a registered trademark of DuPont
[3] Formpeel®-T is registered trademark of Coveris

packaging cardboard boxes with a craft layer of bleached white paper cannot be replaced. The bleaching processes used for the white cardboard materials are either **Elementary Chlorine Free (ECF) or Total Chlorine Free (TCF).**

Avoidance of unnecessary packaging materials and the use of the smallest possible packaging also represent our sustainability efforts. However, the cardboards are laid out with recyclable PE bags made of LD-PE due to clean room handling and sterilisation issues. An important criterion for material selection is, amongst others, the sterilisation resistance.

The labels on the secondary/tertiary packaging consist of cellulose based materials.

Packaging overview

Secondary packaging

Primary packaging

Primary packaging

Packaging recycling

All packaging materials used for packaging of CODAN's medical devices are in compliance with **Directive 94/62/EEC on Packaging and Packaging Waste.** This means i.a. that the sum of concentration levels of heavy metals contained in primary and secondary/tertiary packaging does not exceed the limits according to **article 11 of this Directive.**

The secondary/tertiary packaging made of **cardboard** is **marked with the RESY symbol.** Only recyclable packaging made of paper and cardboard may bear the RESY symbol. Paper and cardboard-based packaging are designed so that all non-paper components used in its manufacture are recycling-friendly. These components do not necessarily have to be recyclable, but they should not hinder the recycling of the base packaging material.
For cardboard boxes used as secondary packaging to protect sterile barrier systems, the percentage of recycled corrugated cardboard is 100 %.
For white cardboard used for reusable non-sterile accessories, the recycled content of the corrugated cardboard is at least 75 %.

In order to indicate that the secondary/tertiary packaging boxes are made of corrugated cardboard, they are labelled with the PAP20 symbol. The symbol also indicates that the cardboard packaging can be disposed of with the used paper.
PE bags to lay out cardboards used for soft film sterile barrier systems due to clean room handling and sterilisation issues are recyclable and labelled with a recyclingcode indicating the material (LD-PE).

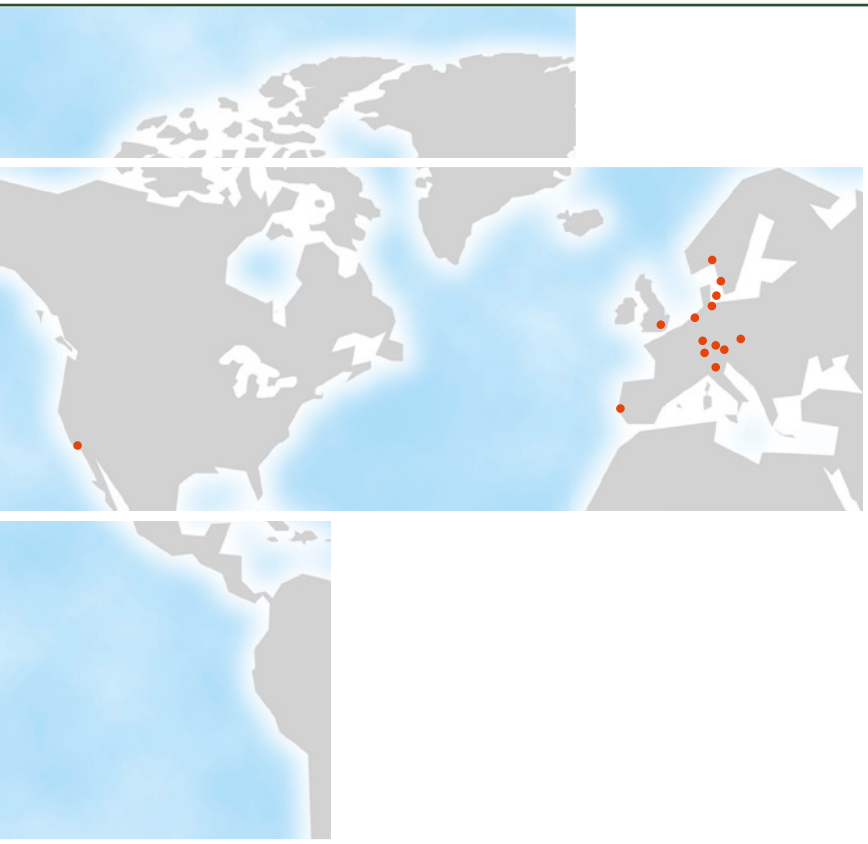
The design guidelines of the Healthcare Plastic Recycling Council recommend switching from standard composite materials to packaging solutions made of mono-material. The Healthcare Plastic Recycling Council's design guidelines recommend switching from standard composite materials to mono-material packaging solutions.
CODAN pvb CC has been implementing these guidelines for more than 10 years with the use of the easily recyclable solutions Tyvek® 2FS™ 2 and PE Formpeel®-T3.

Tyvek®1 is made of high-density polyethylene (HDPE) and is recyclable. Tyvek®1 is a 100 % synthetic material made from high-density spunbound polyethylene fibers. Only products made of 100 % Tyvek®1 material can be recycled. Therefore, if the film is separated from the Tyvek®1, the Tyvek®1 can be 100 % recycled in facilities that recycle flexible HDPE materials. But even if the Tyvek is not separated from the soft film, the complete packaging can be recycled with a very high recyclate yield according to the supplier's information.

We would like to inform you that, according to the information provided by the manufacturer and supplier of the packaging material, the packaging solution of the sterile packaging consisting of Formpeel®-T3 in combination with Tyvek®1 was tested by the independent institute cyclos-HTP to determine the recyclability of the entire packaging solution. The combination of Formpeel®-T3 and Tyvek®1 achieved a high level of recyclability (> 90 %).

These results confirm that the material combination is easily recyclable and represents a particularly sustainable solution compared to the standard packaging of our competitors.

CODAN Worldwide



CODAN is known internationally as a manufacturer and supplier of medical transfer systems. The CODAN Companies have more than 1500 employees around the world.

The name CODAN is synonymous with reliability, quality and precision based on the know-how and experience gained from more than 60 years of research and development. Company-owned production facilities and sales companies around the world are a guarantee for efficient production, a tight-knit sales network and a first-class service for customers in the healthcare sector.

CODAN Product range

- Infusion sets
- Transfusion sets
- Extension lines and manifold connectors
- Infusion and transfusion accessories
- Infusion filters and filter systems
- Neonatology/Paediatric products
- Withdrawal, preparation and administration systems
- CODAN CYTO®
- Chemoprotect® products
- Single use syringes
- Invasive blood pressure monitoring systems
- Infusion pumps
- Other CODAN Products

CODAN Companies

CODAN Medizinische Geräte GmbH · Deutschland
CODAN pvb Critical Care GmbH · Deutschland
CODAN pvb Medical GmbH · Deutschland
CODAN 11, S.A. · Portugal
CODAN US Corporation · California · USA
CODAN Inc. · California · USA
CODAN NORGE AS · Norge
CODAN TRIPLUS AB · Sverige
CODAN Limited · Great Britain
CODAN FRANCE Sarl · France
CODAN Medical AG · Schweiz
CODAN ARGUS AG · Schweiz
CODAN BV · Nederland
CODAN s.r.l. · Italia
CODAN Medical GmbH · Österreich
CODAN Medical ApS · Danmark
CODAN DEHA ApS · Danmark
CODAN MEDITECH s.r.o. · Česká republika

Compliance of the established quality management systems with the provisions of EN ISO 13485, the Council Directive 93/42/EEC and/or Regulation (EU) 2017/745 has been certified by the relevant, competent notified bodies:

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The decisive connection

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