CODAN Packaging

CODAN Medizinische Geräte GmbH

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CODAN Medizinische Geräte GmbH (CODAN) feels responsible for the preservation of the environment and has therefore implemented and maintains an **Environmental Management System (EMS)** according to **EN ISO 14001** as well as an **Energy Management System (EnMS)** which is certified according to **EN ISO 50001**.

To the greatest possible extent, CODAN considers it important to balance the interests of business, applicable regulations and medical demands with the needs of environmental and climate protection. CODAN strives to keep environmental impacts at the lowest possible level.

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. To ensure continuous improvement of CODAN's environmental performance, appropriate environmental reports are submitted to the management at least once a year.

The medical devices produced and placed on the market by CODAN are developed in accordance with **EN ISO 13485:2016** and comply with Regulation **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 Materials etc.).

In accordance with MDR, CODAN as manufacturer of medical devices provides the user with information on safe disposal of the product. Likewise, the MDR stipulates 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 is manufacturer of sterile single-use medical devices (class Is/IIa). 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 (maximum of 5 years after date of manufacturing). Sterile packaging is regulatorily considered as part of the product. Sterile medical devices from CODAN are packed in so-called sterile barrier systems (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 MDR, the packaging configurations of CODAN's 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, CODAN has to verify the material properties like **sterilisation resistance, microbial barrier properties, integrity of packaging, etc.** throughout the entire supply chain process (storage, transport, unpacking, use and disposal) and the associated challenges for a safe medical device as part of the packaging validation processes for the respective packaging systems. This also includes ensuring that the packaging of our medical devices has **no sharp or protruding parts that could cause injuries to users, patients or third parties.**

Primary packaging

Materials primary packaging:
Sterile barrier systems
CODAN uses sterile barrier systems made of thermoformed (multilayer) films sealed against an upper web made of medical paper or Tyvek®[1].

In principle, two kinds of film material are used: rigid film (made of Amorphous-Polyethylene Terephthalate (APET) polymer material with a Polyethylene (PE) sealing layer) or soft film (made of Polyamide/Polyethylene (PA/PE) polymer or Polyethylene/Polyamide/Polyethylene (PE/PA/PE) polymer with a Polyethylene (PE) sealing layer).

The selection of materials (rigid or soft film/medical paper or Tyvek®) depends on the medical device that is packed. 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.

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. The packaging is marked with the respective label. The bleaching processes used for the 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 either laid out with recyclable PE film (used for rigid film sterile barrier systems) or bundled up in recyclable PE film (used for most soft film sterile barrier systems) 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.

[1]Tyvek® is a registered trademark of DuPont

Packaging overview

Packaging recycling

All packaging materials used for packaging of CODAN medical devices are in compliance with **Directive 94/62/EEC on Packaging and Packaging Waste**. This means inter alia 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 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, 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.

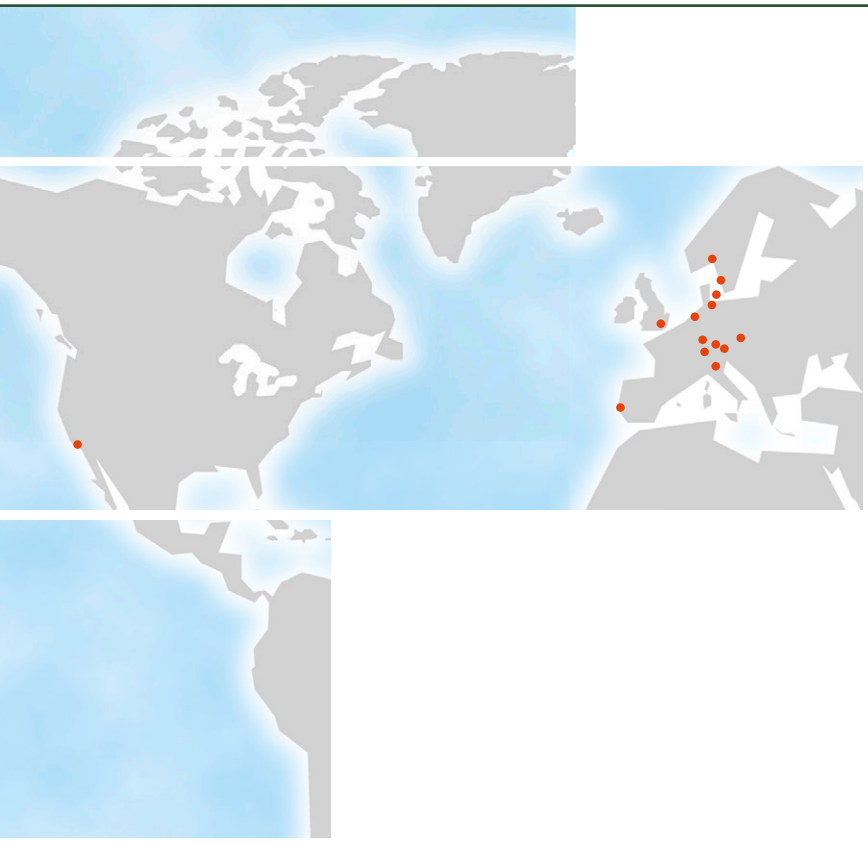
The secondary/tertiary packaging made of **cardboard** is **marked with the respective forest certification mark/ recycling symbol**. Smaller units of CODAN medical transfer devices are often wrapped in bundle film (PE) to facilitate handling in practice and hospital logistics up to the ward. This way, the cardboard boxes can remain directly in the storage area to support feeding into recycling.

The PE bundle film is also recyclable. This also applies to the PE film used to lay out cardboards for rigid film sterile barrier systems.

According to the information obtained by our suppliers, the used films of our sterile barrier systems (rigid or flexible films) are not recyclable. In case of the readily recyclable APET film, this is due to the fact that the material must additionally contain a PE sealing layer which is sealed against the upper web. The composite films (made of PA/PE or PE/PA/PE) must be used for flexible packaging as the large number of components in our medical devices requires the use of highly pinhole resistant films. Unfortunately, composite materials cannot be fed into a recycling process in regards of possible contamination and unmixed separation.

This also applies for the Tyvek®[1] material which consists of spun bond olefin fibres and the medical paper due to the respective refinement processes. The Tyvek®[1] material itself is 100 % recyclable.

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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