

TECHNICAL DATA SHEET

CB Healthcare Consulting GmbH confirms the following information for the Self-Sealing Sterilization Pouches listed below:

REF	Description
9792148	DE Selfseal pouch 83 * 159mm
9792149	DE Selfseal pouch 89 * 254mm
9792150	DE Selfseal pouch 134* 280mm
9792227	DE Selfseal pouch 70 x 254 mm
9792494	DE Selfseal pouch 57 x 133 mm

Intended use:

For use as packing material for medical devices in sterilization by steam, ethylene oxide gas in healthcare establishments. The Self-Sealing Sterilization Pouches are single use.

Process indicators

With multi-parameter internal and external indicators made of water-based (environmentally friendly), lead-free, non-toxic ink

Sterilization:

Compatible with Steam and Ethylene Oxide (EO) sterilization methods.

Steam: changing colour from pink to cacao

EO changing colour from blue to golden brown

Pouches maintain sterility of the device for up to one year post sterilization (if correct storing conditions are followed)

Material:

Pouches and corresponding packaging is latex-free.

Non-tearing, thick multi-layer film made from a combination of polypropylene and polyethylene. Transparent, blue tinted film facilitates both easy instrument viewing and identification of puncture or tears in the film.

All imprints placed outside the actual packaging area – no ink-contaminated of the items. High quality, porous 60 g/m² medical grade paper.

Sealing:

Strong, thermal single seal. Extra wide chevron and fixed corner.

Pouches have a wide adhesive sealing tape which easily and securely seals the pouch providing a reliable seal until pouch is opened. Perforated fold facilitates quick and accurate folding of adhesive strip to form airtight seal.

Clean, fiber-free separation of paper and film ensures safe presentation of sterile products. Thumb notch assures easy opening of pouch.

Regulatory:

Class I, CE. Made in accordance with EN 868-5, ISO 11140-1, and ISO 11607-1.

Shelf-life:

The shelf life is 36 months from the date of manufacture.

Please do not hesitate to contact us if you have any questions or comments.