

AUTOSEALING POUCHES FOR STEAM AND EO STERILIZATION

Autosealing pouches are made by a medical use plastic material called laminated transparent film produced in green or light blue colours which comes from a special film of crown medical polyester (PET) and shutter-less medical polypropylene (CPP) and medical paper (STERIKRAFT).

This paper, certified BILLERUD STERIKRAFT S conforming to ISO 11607-1:2009 analysis in accordance with UNI EN 868-3:2009 and UNI EN 868-6:2009, results issued by ISEGA certificate 625 P 09 dated 29/10/2009, standard type 60gr/sqm and only on special request by customers we can produce with 70gr/sqm. This paper has produced by an high technological system in white colour and it has been studied to assure an high anti-bacterial protection; an excellent functionality for medical sterilization, a certified porosity and contributes both to strength and pelability of sealings. The printing is with indicators, one for steam sterilization and one for ethylene oxide sterilization (EO). The inks used are water basis and non-toxic regularly certified by norm ISO 11140. The paper follows a printing process on sealings and anyway outside the centre of the autosealing pouches in all sizes.

Laminated film for both materials PET and CPP is conforming to: ASTM D882, D1894, D2578, D1505, D1003, D1204, F1249, D3985.

Besides, it is produced in a quality system as registration of relative suppliers.

Neutral medical paper produced by BILLERUD is conforming to ISO 11607 and EN 868 and follows what stated in the following norms: ISO 536, ISO 5636, ISO 1924, ISO 3781, ISO 1974, ISO 2758, ISO 3689, ISO 8791, ISO 535, ISO 6588, ISO 9197, ISO 9198 and it is produced in a quality system as registration of relative supplier.

Autosealing pouches are certified and produced following international standards ISO 11140, ISO 11607-1:2009, ISO 11607-2:2006, ASTM F1980:2007M UNI EN ISO 868-2:2009, UNI EN ISO 868-5:2009 with registration by Ministry of Health in Italy with manufacturer number 5843 and system progressive issued by DM 112762/R and classification CND S01020101,

Autosealing pouches are used for steam or ethylene oxide process sterilization of single items; the correct sterilization is certified, at correct temperatures, by the change of indicators colours: for ethylene oxide sterilization temperature is 30° C - 54° C and the colour changes from light blue to yellow/brown; for steam sterilization temperature is 121° C - 134° C and the colour changes from pink to brown.

Change indicators must have a minimum area of 100MM² and placed in order to avoid any possible contamination with the product inside to be sterilized.

Autosealing pouches can be sterilized only once because it is a DISPOSABLE medical device CE Class I as per EUROPEAN DIRECTIVE 93/42/CEE, and further modifications as per European Directive 2007/47/CEE, DISPOSABLE so one use it has to be thrown away because it cannot be used for a second sterilization cycle.



It is forbidden using the autosealing pouch if it is damaged.

Besides, we inform the end-user that the autosealing pouch has to avoid the sunlight and it has to be stored in a dry place; the autosealing pouch has to be used only after having checked that no dust is on its packing and if it is partially used, it must be hermetically closed in its plastic protection.

Lot number, made by 2 letters and 6 numbers, has to be read as specified here as follows:

- first two letters identify the lot of the film used;
- third number identifies the operator which works on the production machine at that moment
- last numbers identify the date using the following criteria: first two numbers are the day, further two numbers are the month and the latest one is the year of production.

Lot number is printed on the inner box and on its outer carton packing in order to assure the total traceability of the product also due to the technical and production documents kept in our office for 8 years.

We would like to point out that the lot number printed on paper used to produce autosealing pouches has not be considered for possible claims because it identifies the lot of the supplier of raw material.

Autosealing pouch (not even sterilized) can be used within **8 years** from production date considering that the box, if opened, has to be suitably closed and stored far from strong light, heat, humidity and cold. On each inner box there is printed the date of production and expiry.

Sterility expiry for EO and STEAM depends on many factors such as the type of sterilization cycle, the place in which sterilized product is stored and it changes following a lot of parameters as per our CIRCOLARE DURATA STERILITA' Edizione 0 dated 08.08.2007.

Our delivery method is based on FIFO (first in - first out); this means that the material is delivered in order of production' date (the items get out of warehouse in chronological order) and we recommend users to do the same in order to have in stock only the latest lots.

Technically, the hot sealings are "Multiline" and made by bars with regular width (with minimum 9 mm and maximum 12 mm) and distance in order to assure higher resistance to pressure rises and to burst; they also grant the needed pelability.

Autosealing pouches assure a packaging with an high technological quality content in order to satisfy the different needs of packaging in hospital, dental and industrial fields.

Autosealing pouches are packed into inner boxes and put into a carton in order to protect them from dust and humidity.

Autosealing pouches are checked conforming UNI ISO 2859-01 following AQL 0,65 S.I.L. S-2 for functional and dimensional controls and AQL 1,5 G.I.L. I for visual controls.

AQL means "Acceptable Quality Level" and for each lot and on the total quantity we check the products at random with a special and strict criteria.

Traction dynanometric evidences, sealings integrity evidences, pelability evidences and aging process evidences have been valued and showed in

Cautions:

- 1) before starting sterilization process, please, check that autosealing pouch is filled for maximum $\frac{3}{4}$ of its volume so that sealings are not obstructed at the edges;
- 2) cover the end and the cutting surfaces of instruments with appropriate protection;
- 3) put the instruments with the handle at the opening of the autosealing pouch;
- 4) do not use solvent substances on the autosealing pouch;
- 5) possible printings have to be written on a label and stucked on paper or film side; please do not write directly on autosealing pouch and, anyway, use the maximum care to avoid contamination problem during the use;
- 6) Please carefully check the weight of the instruments to be sterilized in order to avoid risks of breaking.

TECHNICAL DETAILS

Steam indicator colour : from pink to brown

We would like to point out that the ink used for steam indicator is not a graphic printing ink. It is a chemical process ink. The sterilization process causes a chemical reaction which causes a colour change. The reaction is based on many variables and the user can expect a final colour that changes from light brown to medium brown as per certification of ink's producer.

Steam sterilization temperature : 121°C - 134°C

EO Gas indicator colour: from light blue to yellow/brown

We would like to point out that the ink used for eo gas indicator is not a graphic printing ink. It is a chemical process ink. The sterilization process causes a chemical reaction which causes a colour change. The reaction is based on many variables and the user can expect a final colour that changes from the light blue to yellow/brown as per certification of ink's producer.

EO Gas sterilization temperature : 30°C - 54°C



AUTOSEALING POUCHES

s.r.l.

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CODE

A60x110

SIZE

mm.60x110 film length
mm.60x140 paper length

PACKING

200 pouches/box
24 boxes/carton = 4800 pcs

A70x230

mm.70x230 film length
mm.70x260 paper length

200 pouches/box
8 boxes/carton = 1600 pcs

A90x130

mm.90x130 film length
mm.90x160 paper length

200 pouches/box
14 boxes/carton = 2800 pcs

A90x230

mm.90x230 film length
mm.90x260 paper length

200 pouches/box
8 boxes/carton = 1600 pcs

A90x330

mm.90x330 film length
mm.90x360 paper length

200 pouches/box
4 boxes/carton = 800 pcs

A140x250

mm.140x250 film length
mm.140x295 paper length

200 pouches/box
6 boxes/carton = 1200 pcs

A140x330

mm.140x330 film length
mm.140x360 paper length

200 pouches/box
4 boxes/carton = 800 pcs

A190x330

mm.190x330 film length
mm.190x360 paper length

200 pouches/box
4 boxes/carton = 800 pcs

A230x365

mm.230x365 film length
mm.230x400 paper length

100 pouches/box
1 box = 1 carton

A300x370

mm.300x370 film length
mm.300x410 paper length

400 pouches/carton
1 carton

A330x440

mm.330x440 film length
mm.330x470 paper length

200 pouches/carton
1 carton


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