

Instructions For Use



EN INSTRUCTIONS FOR USE

REF BM330025028 - AP | Sterilization pen black

REF BM330025030 - AP | Sterilization pen blue

Intended use

The Sterilization pen is intended to be used to clearly add writing on the film of pouches, the tape on sterilization wrappings or ID-Hanglabels. The ink of the Sterilization pen is immediately dry, waterproof and is non-toxic.

Instruction for use of the product

- Use the pen to write on packaging to identify packages when going through the sterilization process.
- Uncap the pen.
- Write permanent, reliable markings or other writing on the film of pouches and/or the tape on sterilization wrappings and/or on ID-Hanglabels.
- Re-cap the pen after use.

Intended users

- For professional use only!
- Central Sterile Services Department (CSSD) employees assigned for handling sterilization control products and ancillary products.
- Other professionals assigned for handling sterilization control products and ancillary products.

Indications and contra-indications

Use the product conform the information on the label. Do not use for any other purposes than indicated on the label or as specified under "Intended use".

User specifications

Handle, process and dispose in compliance with your facility/department policy and validated processes for sterilization. Use in compliance with the indicated standards which apply for this product (see Declaration of Conformity).

Standard process values

The Sterilization pen cannot be processed in any way!

Disposal information

Dispose in compliance with your facility/department policy for disposal of all sterilization packaging.

Residual risks

Do not use if any unexpected abnormalities appear in or on the product, such as, but not limited to inequalities in structure and/or color.

Avoid handling that could cause damage to the product or its properties.

Notice: any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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This Instructions for use is issued under the sole responsibility of Blue Medical B.V.. We hereby declare that the Instructions for use specified above meets the indicated standards. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Ms. Monique Buijsman
Operations Manager

Place, date (dd.mm.yyyy) of issue and version:

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