



FAQs

MICRONDEVICES STERILE PACKS

Q1: What are sterile packs?

Sterile packs is the generic name for a range of pharmacy compounding multipacks manufactured and sold by Micronclean Ltd under the MicronDevices branding.

Q2: How are the packs used?

The packs can be used in any pharmacy manufacturing environment to assist with the compounding of pharmaceutical products.

Q3: What is the advantage of sterile packs over single packed devices?

A large number of syringes and other components are typically needed during a compounding session. Having multipacks of components is more efficient.

Q4: How are sterile packs more efficient?

The transfer process is made easier as there are typically fewer packs to sanitise and pass into the critical compounding area. Similarly, there are fewer batch details to transcribe and less packaging waste.

Q5: To whom are the packs normally sold?

A wide range of pharmacy applications use sterile packs including commercial compounders, NHS pharmacies and other European healthcare facilities.

Q6: Have Micronclean always packed the product?

Originally the product was packed by Baxter Healthcare in Thetford, UK under a partnership arrangement with Micronclean. In 2016 it was agreed that Micronclean would take over the packing of the product and this commenced in October 2017.

Q7: Where do Micronclean pack the product?

Micronclean have a purpose-built cleanroom in Skegness, UK which exclusively packs sterile packs.

Q8: What classification is the cleanroom?

The cleanroom is Class 6 (at rest) under EN ISO 14644-1 and also EU GMP Grade C.

Q9: Are the packs classed as medical devices?

The packs of syringes and syringe caps are medical devices and the packs have the CE mark of conformity. Other packs such as compounding needles and dispensing pins are not medical devices and are therefore not CE marked.

Q10: What approvals do you hold?

The unit is registered to BS EN ISO 13485:2016, the quality management system for medical device manufacturers. Micronclean also holds a CE certificate stating compliance with the Medical Device Directive and allowing the CE Mark of conformity to be placed on product.

Q11: Are you audited by any regulatory bodies?

Micronclean are routinely audited by their 'Notified Body', BSI, who are designated by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Q12: Which syringes do you use in your packs?

Micronclean use the BD Plastipak range of syringes. These have been used in medical applications for several decades and are suitable for sterilisation by gamma irradiation.

Q13: What sizes of syringes are available?

1ml, 3ml, 5ml, 10ml, 20ml, 30ml and 50ml.

Q14: What pack sizes do you offer?

There are a wide range of pack sizes. Syringes are normally in packs of 5, 10 or 25.

Q15: How are the packs sterilised?

The packs are sterilised utilising gamma irradiation.

Q16: How do I know the pack is sterile?

Representative product has been validated for sterility in compliance with EN ISO 11137-1. Micronclean have strict controls around product release and will only sell sterile products.

Q17: Do you supply any certification with the product?

Yes, a certificate of conformity is sent with each order. This includes the sterilisation details including the dose achieved.

Q18: What is the shelf life of the packs?

The standard shelf life is three years.

Q19: Can you triple wrap products to help with our transfer process?

Yes, any product code can be triple wrapped on request. Micronclean carry this out on a 'made to order' basis, the lead time for this is typically six weeks.

Q20: Can I visit or audit the packing facility?

Absolutely, yes!

Micronclean welcome visits and audits, please contact us to arrange.

Q21: Do you hold stocks of products?

Yes, Micronclean hold extensive stocks of most products in a dedicated warehouse facility adjacent to the sterile packs assembly cleanroom. Micronclean can also hold dedicated stocks for you, subject to a stock agreement being in place.

Q22: Can you trace your products in the event of a problem such as a product recall?

Yes, Micronclean retains information on all batches of products sold including product code, batch number, date of sale and customer / location.

Also, each individual pack displays a barcode and production and device information which meets the new regulatory requirement for unique device identification (UDI) for medical devices.

Q23: Can you meet the NHS 'scan4safety' requirements?

Yes, Micronclean use the GS1 system of product identification used by the NHS in the Scan4Safety scheme.

Q24: We need a product packing and sterilising, can Micronclean help?

Hopefully yes!

Micronclean have a dedicated product development team who will work with you from initial concept through to final product realisation.