



Micronclean hold both ISO 9000 and ISO 13485 registration which enables the production and distribution of sterile CE marked medical devices.

The Compliance 100® product is a high quality sterile pack designed for use in the healthcare industry. It is fully compliant with the requirements of the Compliance 100® Sterile Pack User Guide.

Production is further enhanced via Micronclean's fleet of delivery vehicles, able to deliver to any location.

Saving Time. Assuring Quality.

Micronclean's **Compliance 100® Sterile Packs** - the next generation in sterile devices



Saving Time, Assuring Quality

A brief history of Micronclean

Micronclean have offered a specialist sterile class 100 cleanroom garment service to manufacturing pharmacies, and industrial compounders since 1982.

The provision of sterile and non-sterile garments is of course both GMP quality driven and a highly detailed activity, this linked to strong 'point of use' logistics involvement and flexibility to cope with the fluctuations of patient drug production, has led to Micronclean becoming market leader in this field.

In 2004, to complement this expertise in GMP processing and logistics, Micronclean launched the Compliance 100® range of GMP products manufactured, processed and supported by Micronclean in the UK. The first Compliance 100® product was the cleanroom mopping system, a system where a microfibre mop, developed in conjunction with FHP Vileda, is processed, impregnated and sterilised. This system remains highly efficacious and has a low cost of ownership, due to the re-processing and logistics systems applied by Micronclean, plus, as the name of the product describes, the automatic rotation of disinfectants ensures compliance with regulatory guidelines requirements.

2006 saw the second member of the Compliance 100® product family launched - the GMP Cleanroom designed wipe range.

This sterile range of wipes was developed solely for GMP usage and includes many variants including IPA/WFI impregnated types and dry versions to meet the highest requirements for cleanroom cleaning and transfer processes. Comprehensive qualification and validation support guides are the cornerstone of these widely used wipes.



Compliance 100® Sterile Packs

Quality Designed Micronclean Compliance 100® Sterile Packs

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The Compliance 100® product is a highly qualified and proven device. Baxter Healthcare at their Thetford facility utilise the full range of product configurations in the manufacture of LVPs.

The qualification of security of these devices is fully detailed and illustrated in the Compliance 100® Sterile Pack Validation Support Guide*.

Product quality is further enhanced via Micronclean's storage and own fleet of delivery vehicles, able to deliver right to the point of requirement.



“The use of pre-pouched manufacturing components has improved production efficiencies to new levels, whilst simplifying batch record keeping”

BHC Manufacturing Manager.



* Reference VG0701A for this document when speaking to Micronclean sales.

The Transfer Process

Given the text from the EU EMP Annex 1 (Rev 2003) which states "The transfer of materials into and out of the unit is one of the greatest potential sources of contamination". It is clear that there is a requirement to provide an additional service to isolator/LAF users to assist in significantly reducing this 'transfer' risk*. By providing a pre-packaged set of sterile components and additionally double pouching each of these 'procedure packs' Micronclean's Compliance 100® Sterile Packs are providing a solution which:-

Reduces alcohol wipe processes to a minimum

- *Reducing risk*
- *Reducing alcohol usage*

Removes excess packaging associated with individually packed components

- *Saving waste, keeping the isolator/LAF use area to a maximum*
- *Reducing particulate (especially when compared to 'paper backed' syringes)*



* Reference paper 'Validation of liquid disinfectant tech for transfer of components into hospital pharmacy cleanrooms'. MG Cockcroft etc et al.



A 'Virtual' Extra Pharmacy Technician

As a consequence of the increased efficiency of transfer times and the enhanced isolator/LAF usable workspace, the opportunity to make the same quantity of final product for less time is realised*.

As each pouch of products has a single traceable batch number (traceable to all the sub-components batch number) the work of the technician in transcribing information is significantly reduced as is the potential for error. This releases valuable technician time, and depending on scale can create a "whole additional" number of staff!

* Up to 7.5 times the volume of components can be transferred into an isolator utilising the same workforce. Ref 'How to minimise contamination when transferring items into hospital cleanrooms'. S. Stubbs, June 2006



Compliance 100® Sterile Packs

Using Vapourised Hydrogen Peroxide (VHP)

Early in the development of the Compliance 100® Sterile Packs it became clear that there are a significant and growing number of isolator users who are successfully employing VHP as the transfer method of choice in their facilities.

The standard Compliance 100® Sterile Pack pouches were designed from the start to be qualified for either alcohol or VHP transfer products.

The benefit to VHP users is a crystal clear pouch, so contents are easily visually confirmed and for those customers who have a mixture of VHP in some areas and alcohol transfer processes in others a single stock item which meets both requirements.

Ease of Access with Enhanced Seal Security

Opening packs of any type whilst gloved in an isolator can be a task, bearing this in mind, Micronclean developed the Compliance 100® pouch with an easy tare nick as standard, enabling easy opening.

The pouches have a wide 10mm heat-sealed edge, allowing easy visual evidence of the post fill seal integrity.

The three pre-formed edge seals are to an equally high specification, and incorporate a zero crevice edge, thus providing confidence that no potential 'protected' bio-burden zone is present, which may adversely effect the efficiency of any spray and wipe process.



Compliance 100[®] Sterile Pack Range

Saving Time, Assuring Quality



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