

MICRONDEVICES

BROCHURE :: 2022





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ABOUT MICRONDEVICES

Micronclean established its MicronDevices business in 2007 (then known as 'Sterile Packs') and throughout that time has developed expertise and knowledge supplying the drug compounding market. We have a dedicated Medical Device Technical Specialist to support our commercial team, customers and maintain our quality and regulatory systems.

Within our dedicated Class 6 cleanroom we have the capability to rapidly develop custom packs to meet customer specific requirements and our in-house software BRC (Batch Record and Control) provides full traceability.

To always ensure continuity of supply to our customers Micronclean does not operate a just in time policy for either its components or finished goods in our warehouse. We have substantial stocks of both to enable immediate order fulfilment.

THE CLEANROOM

In 2017, Micronclean designed, built and qualified a brand new purpose-built cleanroom for the assembly and packing of MicronDevices. The design encompassed state of the art air handling and filtration systems, materials transfer capability, continuous pressure monitoring and a two-stage changing suite.

The cleanroom is fully qualified to ISO 14644-1 Class 6 (at rest) and EU GMP Grade C. In addition to annual re-qualification by specialist cleanroom validation engineers, the cleanroom is surveyed quarterly for particulate levels and every two weeks for microbiological counts. Micronclean have a laboratory in Skegness which has been carrying out environmental testing of the company's various cleanrooms since 1989.

Within the cleanroom are two production lines, each with two stages, inspection and filling. At the inspection stage, each component is visually assessed against documented quality criteria and any defective components are carefully logged and segregated. In the filling stage, product labels are produced and affixed to primary packaging, which is filled with the required components, sealed and then double or triple wrapped according to customer requirements. The packs are then cartonised in the Class 7 transfer room and then palletised for shipment to an approved irradiation facility.



THE TRACKING SOFTWARE

One of the key goals in developing the MicronDevices cleanroom facility was to have a paperless manufacturing process. To meet this goal Micronclean's in-house software development team specified, wrote and implemented bespoke software for the unit – BRC (Batch Record and Control).

BRC has two functions; firstly, it tracks each component used in a pack from the supplier through to finished product. This ensures that full traceability is maintained, via the Micronclean batch number, to all key manufacturing parameters including supplier batches.

Secondly, BRC collates a digital batch record in real time as the batch is being manufactured. Details recorded include component batches and quantities, names of operators, equipment details, label scans and quantity and type of component rejects. Once completed and closed the batch record cannot be amended.

STOCK, TRANSPORT AND SHIPPING

Stock holding is managed by Micronclean's powerful stock inventory software and delivery is direct from Micronclean's own state of the art storage facilities.

Within the UK, our own fleet of vehicles run overnight trunking routes to service our regional transport centres in the South East, South West, North East, North West and Scotland. From these regional hubs, our fleet then undertake local tailored deliveries to ensure that you get all your items when you want them.

As a result, our transport network covers the whole of the UK ensuring that all our customers get an efficient, cost effective and reliable flow of cleanroom items.

For export customers, delivery is made using a variety of shipping routes with the aim to deliver to you the correct balance between delivery time, cost and quality of service. Within the Export Department we have experience of shipping to over 35 countries worldwide covering countries in South America, Europe, India, China and Australia.



REGIONAL LABELS

Following increasing global demand for our syringe packs, we have enhanced our existing product labels to ensure that we remain compliant. To meet labelling regulations, we will continue to carry three languages in addition to English on each label. The additional languages have been logically grouped into geographic regions to enhance our ability to service our export customers.

A

UK

Ireland

Germany

Austria

B

UK

Spain

Portugal

Italy

C

UK

France

Belgium

Holland

D












UK

Sweden

Denmark

Norway

For instance, to service the market in Belgium we must supply a label that carries French, German and Dutch.

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	Sterile Pack / Sterile Packung <div>REF</div>		
	<div>LOT</div> 		
EN Contents IE Contents DE Inhalt AT Inhlalt			
EN IE DE AT			
<div>   <div>STERILE R</div>    <div>PHT DEHP</div>  <div>MD</div>  </div>			



PRODUCT OFFERING

STERILE SYRINGE PACKS

BD Syringe Size	Product Code	Description
1ml	01ML05CC	1ml BD Syringe Sterile 20 Packs of 5
	01ML10CC	1ml BD Syringe Sterile 10 Packs of 10
	01ML25CC	1ml BD Syringe Sterile 10 Packs of 25
	01ML10LS	1ml BD Luer Slip Syringe Sterile 10 Packs of 10
3ml	03ML05CC	3ml BD Syringe Sterile 20 Packs of 5
	03ML10CC	3ml BD Syringe Sterile 10 Packs of 10
	03ML25CC	3ml BD Syringe Sterile 10 Packs of 25
	03ML25CH	3ml BD Syringe and Cap Sterile 10 Packs of 25
	03ML25SC	3ml BD Syringe and Cap Sleeved Sterile 12 Packs of 25
5ml	05ML05CC	5ml BD Syringe Sterile 20 Packs of 5
	05ML10CC	5ml BD Syringe Sterile 10 Packs of 10
	05ML25CC	5ml BD Syringe Sterile 10 Packs of 25
	05ML50CC	5ml BD Syringe Sterile 10 Packs of 50
10ml	10ML05CC	10ml BD Syringe Sterile 10 Packs of 5
	10ML10CC	10ml BD Syringe Sterile 10 Packs of 10
	10ML25CC	10ml BD Syringe Sterile 10 Packs of 25
	10ML25CH	10ml BD Syringe and Cap Sterile 10 Packs of 25
	10ML25SC	10ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25
	10ML50CC	10ml BD Syringe Sterile 5 Packs of 50
20ml	20ML05CC	20ml BD Syringe Sterile 10 Packs of 5
	20ML10CC	20ml BD Syringe Sterile 10 Packs of 10
	20ML25CC	20ml BD Syringe Sterile 10 Packs of 25
	20ML50CC	20ml BD Syringe Sterile 10 Packs of 50
	20ML25SC	20ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25
30ml	30ML05CC	30ml BD Syringe Sterile 10 Packs of 5
	30ML10CC	30ml BD Syringe Sterile 10 Packs of 10
	30ML25CC	30ml BD Syringe Sterile 10 Packs of 25
	30ML25CH	30ml BD Syringe and Cap Sterile 10 Packs of 25
	30ML25SC	30ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25
50ml	50ML05CC	50ml BD Syringe Sterile 10 Packs of 5
	50ML10CC	50ml BD Syringe Sterile 10 Packs of 10
	50ML25CC	50ml BD Syringe Sterile 8 Packs of 25
	50ML25CH	50ml BD Syringe and Cap Sterile 8 Packs of 25
	50ML25SC	50ml BD Syringe and Cap Sleeved Sterile 4 Packs of 25
Caps	50ML300C	50ml BD Syringe and Cap Sleeved Sterile 12 Packs of 25
	CAPS10CC	Syringe Cap Sterile 20 Packs of 10
	CAPS50CC	Syringe Cap Sterile 10 Packs of 50

ISOLATOR SLEEVES

Micronclean can provide pharmacy components in an isolator sleeve (described as 'sleeved' in the table above). Pouches of components are sealed in a long sterile polythene 'sleeve' which can be opened at one end and attached to an isolator port allowing sanitisation of multiple products in one gassing cycle and transfer into the isolator. Isolator sleeves can provide considerable efficiency savings for large compounding sessions when compared with individual pouches. Micronclean can provide custom sleeves in addition to the products listed above.

PHARMACY COMPOUNDING PACKS

Product Code	Description
CDPB25CC	B Braun Chemo Dispensing Pin Sterile 4 Packs of 25
LVDP10CC	B Braun Large Volume Dispensing Pins Sterile 10 Packs of 10
CDPB25CC	B Braun Chemo Dispensing Pin Sterile 10 Packs of 25
BBFC10CC	B Braun Fluid Dispensing Connector Sterile 15 Packs of 10
FRSW25CC	Filter Straw Sterile 10 Packs of 25
19TR50CC	Terumo Needle 19g x 40mm Sterile 10 Packs of 50
21TR25CC	Terumo Needle 21g x 40mm Sterile 10 Packs of 25
21TR50CC	Terumo Needle 21g x 40mm Sterile 10 Packs of 50
18TR50CC	Terumo Needle 18g x 40mm Sterile 10 Packs of 50
19FN25CC	B Braun Filter Needle 19g x 40mm Sterile 10 Packs of 25
ENV200CC	Environmental Label Sterile 10 Packs of 200
BCL200CC	Barcode Label Sterile 10 Packs of 200
PEN005CC	Pen Sterile 20 Packs of 5
SBAG10CC	Waste Bag Sterile 10 Packs of 10
ABAG50CC	Light Inhibiting Bag Sterile

Micronclean supply a wide range of drawing up needles and vial access devices. Additionally, our range of sterile pens, labels and waste bags complement the device range and assist with efficiencies in compounding environments. Micronclean can source and supply most pharmacy compounding components, in addition to the standard products listed above.

REGIONAL ORDERING

The preceding product tables do not the regional product codes for clarity.

However, to ensure that product labels with the correct languages are ordered and dispatched please ensure that the correct regional suffix is ordered as per the tables on page 4.

So, for instance a product for use in the German market the order code would change from 50ML25CH to 50ML25CH-A, while the same product for use in the Spanish Market would have an order code of 50ML25CH-B.

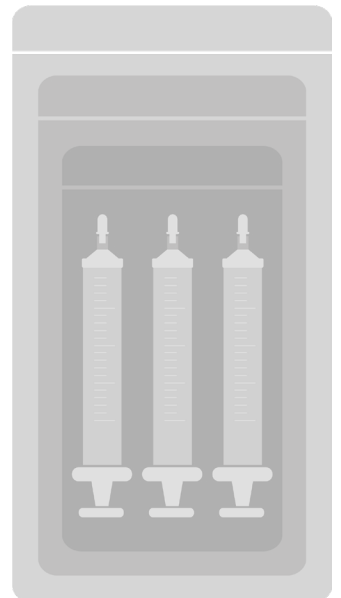




OPTIONAL TRIPLE WRAPPING

Many end users of critical products remove layers of packaging as part of a controlled transfer process. Having three layers of sterile packaging can enable end users to remove costly sanitisation steps from their transfer process saving both time and the cost of sanitising agents.

Micronclean have validated their packaging system to ensure pouch and seal integrity, clarity and sterilisation compatibility and are able to offer triple wrapping across our entire Sterile Packs range.



CUSTOM PACKS

Micronclean offer a customised pack service, developing bespoke packs to meet end users' compounding needs.

Many end users want the convenience of having all of the required components for a compounding session in one sterile pack. Contents typically include a combination of syringes, syringe caps, drawing up needles and vial access devices. Ancillary products to assist compounding such as alcohol wipes, pens, labels and waste bags can also be added to the sterile pack.

Micronclean will manage the entire process, working with the customer to design the pack contents, the packaging and labelling, sterilisation controls and ensuring regulatory compliance. Micronclean offer a range of stock and delivery options and have an extensive transport fleet covering the UK.

New custom packs can be developed within a few weeks, from initial enquiry to quotation, sample pack development and actual manufacture, sterilisation and warehousing.

NOTES



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MCSPB 09/2022