



STERILE PACKS BROCHURE



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ABOUT STERILE PACKS

Micronclean established its Sterile Packs business in 2007 and throughout that time has developed expertise and knowledge supplying the drug compounding market. We have a dedicated Medical Device 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 ensure continuity of supply to our customers at all times 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 fulfillment.





THE CLEANROOM

THE CLEANROOM

In 2017, Micronclean designed, built and qualified a brand new purpose-built cleanroom for the assembly and packing of MicronDevices Sterile Packs. 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 Sterile Packs 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.

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

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	B	C	D
UK	UK	UK	UK
Ireland	Spain	France	Sweden
Germany	Portugal	Belgium	Denmark
Austria	Italy	Holland	Norway

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

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EC REP TBC
 XXX
 YYY
 Imported By TBC
 XXX
 YYY

Sterile Pack / Paquet Sterilé / Sterile Packung / Paquete Estéril	
REF	
LOT	
EN Contents FR Contenu DE Inhalt ES Contenido	
EN May be used (under qualified conditions) in syringe pumps set to the BD Plastipak setting FR Peut s'utiliser (dans des conditions approuvées) dans des pompes-seringues après sélection du réglage BD Plastipak DE Kann (nach entsprechender Testung durch den Anwender) mit Spritzenpumpen verwendet werden. Hierzu muss die Einstellung für BD Plastipak gewählt werden ES Puede utilizarse (bajo condiciones aprobadas) en bombas de jeringa configuradas conforme al ajuste de BD Plastipak	
STERILE R	



PRODUCT OFFERING



STERILE SYRINGE PACKS

STERILE SYRINGE PACKS				
BD Syringe Size	Product Code	Description	Items per pouch	Pouches per carton
1ml	01ML05CC	1ml BD Syringe Sterile 20 Packs of 5	5	20
	01ML10CC	1ml BD Syringe Sterile 10 Packs of 10	10	10
	01ML25CC	1ml BD Syringe Sterile 10 Packs of 25	25	10
	01ML25SC	1ml BD Syringe and Cap Sleeved Sterile 12 Packs of 25	25	12
3ml	03ML05CC	3ml BD Syringe Sterile 20 Packs of 5	5	20
	03ML10CC	3ml BD Syringe Sterile 10 Packs of 10	10	10
	03ML25CC	3ml BD Syringe Sterile 10 Packs of 25	25	10
	03ML25CH	3ml BD Syringe and Cap Sterile 10 Packs of 25	25	10
	03ML50CC	3ml BD Syringe Sterile 10 Packs of 50	50	10
	03ML25SC	3ml BD Syringe and Cap Sleeved Sterile 12 Packs of 25	25	12
5ml	05ML05CC	5ml BD Syringe Sterile 20 Packs of 5	5	20
	05ML10CC	5ml BD Syringe Sterile 10 Packs of 10	10	10
	05ML25CC	5ml BD Syringe Sterile 10 Packs of 25	25	10
	05ML25CH	5ml BD Syringe and Cap Sterile 10 Packs of 25	25	10
	05ML50CC	5ml BD Syringe Sterile 10 Packs of 50	50	10
10ml	10ML05CC	10ml BD Syringe Sterile 10 Packs of 5	5	10
	10ML10CC	10ml BD Syringe Sterile 10 Packs of 10	10	10
	10ML25CC	10ml BD Syringe Sterile 10 Packs of 25	25	10
	10ML25CH	10ml BD Syringe and Cap Sterile 10 Packs of 25	25	10
	10ML25SC	10ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25	25	8
	10ML50CC	10ml BD Syringe Sterile 5 Packs of 50	50	5
20ml	20ML05CC	20ml BD Syringe Sterile 10 Packs of 5	5	10
	20ML10CC	20ml BD Syringe Sterile 10 Packs of 10	10	10
	20ML25CC	20ml BD Syringe Sterile 10 Packs of 25	25	10
	20ML25SC	20ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25	25	8
	20ML50CC	20ml BD Syringe Sterile 10 Packs of 50	50	10
30ml	30ML05CC	30ml BD Syringe Sterile 10 Packs of 5	5	10
	30ML10CC	30ml BD Syringe Sterile 10 Packs of 10	10	10
	30ML25CC	30ml BD Syringe Sterile 10 Packs of 25	25	10
	30ML25CH	30ml BD Syringe and Cap Sterile 10 Packs of 25	25	10
	30ML25SC	30ml BD Syringe and Cap Sleeved Sterile 8 Packs of 25	25	8
50ml	50ML05CC	50ml BD Syringe Sterile 10 Packs of 5	5	10
	50ML10CC	50ml BD Syringe Sterile 10 Packs of 10	10	10
	50ML25CC	50ml BD Syringe Sterile 8 Packs of 25	25	8
	50ML25CH	50ml BD Syringe and Cap Sterile 8 Packs of 25	25	8
	50TB25CC	50ml BD Syringe Trpl Wrppd Sterile 8 Packs of 25	25	8
	50ML25SC	50ml BD Syringe and Cap Sleeved Sterile 6 Packs of 10	10	6
	50ML300C	50ml BD Syringe and Cap Sleeved Sterile 12 Packs of 25	25	12
	CAPS10CC	Syringe Cap Sterile 10 Packs of 10	10	10
	CAPS50CC	Syringe Cap Sterile 10 Packs of 50	50	10

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.



OTHER PHARMACY COMPOUNDING PACKS

Product Code	Description	Items per pouch	Pouches per carton
CDPB25CC	B Braun Chemo Dispensing Pin Sterile 4 Packs of 25	25	4
LVDP10CC	B Braun Large Volume Dispensing Pin Sterile 10 Packs of 10	10	10
COSP25CC	Codan Dispensing Pin Sterile 10 Packs of 25	25	10
BBFC10CC	B Braun Fluid Dispensing Connector Sterile 15 Packs of 10	10	15
18TR50CC	Terumo Needle 18G x 40mm Sterile 10 Packs of 50	50	10
19TR50CC	Terumo Needle 19G x 40mm Sterile 10 Packs of 50	50	10
21TR25CC	Terumo Needle 21G x 40mm Sterile 10 Packs of 25	25	10
21TR50CC	Terumo Needle 21G x 40mm Sterile 10 Packs of 50	50	10
19GN50CC	B Braun Needle 19G x 40mm Sterile 10 Packs of 50	50	10
21GN50CC	B Braun Needle 21G x 40mm Sterile 10 Packs of 50	50	10
19FN25CC	B Braun Filter Needle 19G x 40mm Sterile 10 Packs of 25	25	10
BCL200CC	Barcode Label Sterile 10 Packs of 200	200	10
ENV200CC	Environmental Label Sterile 20 Packs of 200	200	20
PEN005CC	Pen Sterile 20 Packs of 5	5	20
SBAG10CC	Waste Bag Sterile 10 Packs of 10	10	10
ABAG50CC	Light Inhibiting Bag Sterile 3 Packs of 50	50	3

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.



TRIPLE WRAPPING

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.

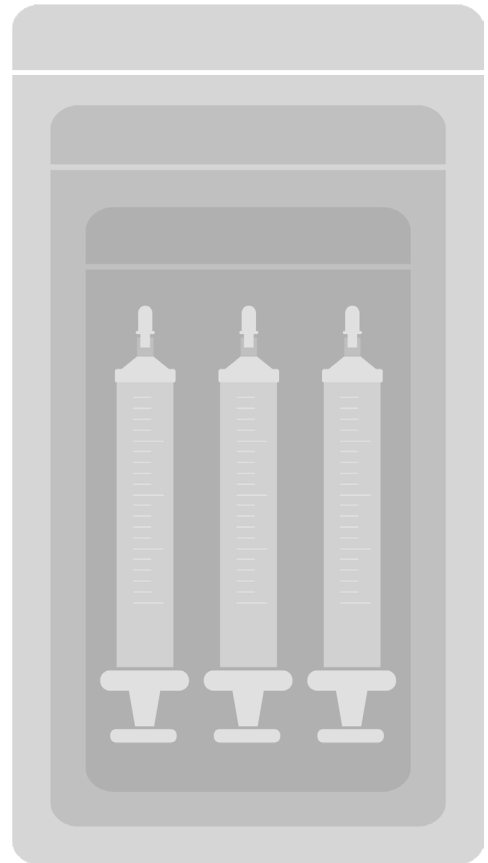
CUSTOM PACKS

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.







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