

Compliance 100®



GMP Wipes designed *specifically* for regulated industries





The Compliance 100® Process

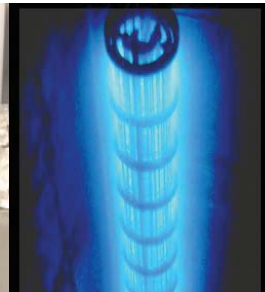
- ④ Security of supply - all products and process steps are dual sourced
- ④ UK manufacture - decontamination, packaging, impregnation and sterilisation
- ④ UK base - easy to audit with full European support
- ④ Full supply chain management - flexible stock and supply
- ④ Micronclean's own transport and distribution
- ④ Electronic process data capture, GMP batch documentation and validation support guide
- ④ Validated processes supported by in-house microbiology and particulate testing
- ④ Bespoke product development via in-house R & D group



Decontamination and primary packaging in Micronclean's Class 100 area



Impregnation with alcohol in Class 100 area



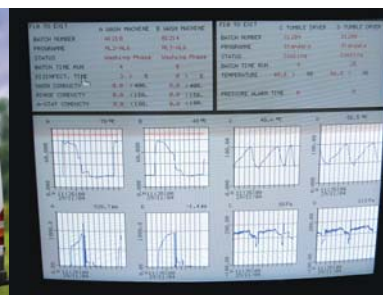
Qualified Gamma sterilisation of all wipe products



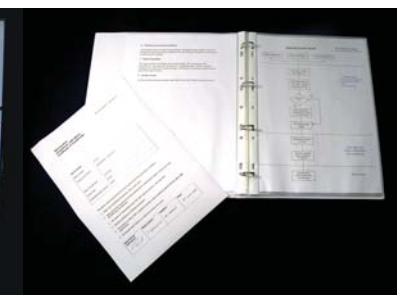
Auditing our facilities and systems



Micronclean's fleet of vehicles can deliver directly to site on a regular basis. Packaging waste recycling can be undertaken



Electronic data capture for batch control



Validation guide and certification

RAW MATERIALS SUPPLY

Dual supply capability in each case

WIPE CONSTRUCTION

IPA MANUFACTURE

POUCH MANUFACTURE

Incoming goods -
QC approval

ISO 14644 Class 4 / EU GMP
Class B decontamination and
primary packaging

Dose with IPA

IPA dosing under Laminar air
flow Class 4 / EU GMP Class B

Final packing and
batch paperwork

No

Sterilisation validated at 25 kGy

Final QC approval and certificate
of conformity and analysis

Distribution by Micronclean's
own transport fleet

MICRONCLEAN

- Multi-site back-up capability
- BS EN ISO 9001:2000
- GMP
- Validated processes

Dual approved
gamma irradiation
sub-contractors

Micronclean
distribution fleet



Compliance 100® - The Product

- A unique range of wipe fabrics - bringing cutting edge products to Europe.
- Application solutions are met by single and dual layer wipes
 - *Single layer products are predominantly used for the 'transfer process'*
 - *Dual layer wipes have superior performance when decontaminating large area hard surfaces within cleanrooms.*
- IPA 70% / WFI 30% impregnation - the highest quality and most cost effective way to apply alcohol in your cleanroom.
- GMP design and manufacture - the entire focus of the Compliance 100® wipe development programme is centred on the requirements of GMP regulated industry use.
- Flexible packaging & product configuration options - low cost bespoke products to meet localised special requirements.
- Packaging UK and EU compliant - no issues with SHE, transport or storage throughout Europe, plus no 'hidden' carrier costs when the Micronclean transport fleet is used.
- GMP compliant documentation supplied with each batch of product - fully traceable to all components and processes.
- Comprehensive validation support guide - available from your sales person, this guide covers the process of manufacture of wipes from raw materials testing to final goods release.



Dual layer wipe in use



Front seal pouch being opened (50 times resealable)



Edge seal pouch in use - a completely mechanical seal with over 50 open/close actions

The 'Compliance 100® Range of GMP Cleanroom Wipes

Description	Hard surface wipe for Class 100 use. Dual layer construction. wt = 264 gm/M ²	Transfer Process wipe for Class 100 use. Single layer construction. wt = 200 gm/M ²	Transfer Process wipe for Class 100 use. Single layer construction. wt = 200 gm/M ²	Secondary area wipe. For Class 1000 or below. Single layer construction. wt = 100 gm/M ²
Reference code	MHPELD25S	MCPELD05S MCPELD50S MCDELN25S MCDELN50S	MCZSLA50S	MLHCSD05S MLHCSD25S MLHCNS00S MLHSSNI0S
Fabric type	100% Polyester	100% Polyester	100% Polyester	Poly/Viscose
Edge finish	Heat sealed x 4	Laser cut x 4	Laser cut x 4	Die cut
Wipe size mm	300 x 300	300 x 300	300 x 300	250 x 250
Gamma sterilised at 25Kgy	Yes	Yes	Yes	Yes
No. of wipes per pouch	25	MCPELD05S = 5 MCPELD50S = 50 MCDELN25S = 25 MCDELN50S = 50	50	MLHCSD05S = 5 MLHCSD25S = 25 MLHCNS00S = 100 MLHSSNI0S = 10 x 10
No. of wipes per carton	250	MCPELD05S = 250 MCPELD50S = 500 MCDELN25S = 500 MCDELN50S = 500	500	500
Primary packaging	Edge re-sealable pouch	Edge re-sealable pouch	Front re-sealable pouch	One use pouch
Secondary packaging	Triple packed	Triple packed	Triple packed	Double packed
IPA USP 70% WFI USP 30% impregnated	Yes	MCPELD05S = Yes MCPELD50S = Yes MCDELN25S = Dry MCDELN50S = Dry	Yes	MLHCSD05S = Yes MLHCSD25S = Yes MLHCNS00S = Dry MLHSSNI0S = Dry



Key components undergoing routine microbiology testing at Micronclean



Testing for particulate cleanliness of processed wipes is performed at Micronclean using the Helmke drum method



Specific packaging, format and impregnation development is routinely undertaken by Micronclean's R & D Department

Quality Assurance

Micronclean is registered to BS EN ISO 9001:2000. The cleanroom facilities are fully validated and all processes are covered by standard operating procedures. Micronclean carries out in-house microbiological testing and analysis of non-viable particulate contaminants. Micronclean are regularly audited by pharmaceutical, industrial and hospital cleanroom customers. Micronclean were the first laundry in the UK to become registered to BS EN ISO 14001:1996 at its Grantham and Louth facilities. Micronclean is a trading name of Fenland Laundries Ltd.



Micronclean

Roman Bank, Skegness, Lincolnshire PE25 1SQ

T: 01754 767377

F: 01754 898392

W: www.micronclean.com

E: enquiries@micronclean.co.uk

Micronclean Louth

Lincoln Way, Fairfield Industrial Estate, Louth LN11 0WX

Micronclean Grantham

Swingbridge Road, Earlsfield Industrial Estate, Grantham NG31 7SF

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