

MICRONCLEAN SUPPORT

TO ADVANCED THERAPY MEDICINAL PRODUCTS

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MEETING THE DEMANDS OF INNOVATION WITH PROVEN CONTAMINATION CONTROL

Advanced Therapy Medicinal Products (ATMPs) represent an innovative class of medicines that utilise genes, cells or tissues to treat, prevent or potentially cure a wide range of diseases. These pioneering therapies are transforming modern medicine and fall into three primary categories:

Gene Therapy Medicinal Products - Deliver therapeutic, prophylactic, or diagnostic effects using functional genetic material.

Somatic-Cell Therapy Medicinal Products - Employ manipulated cells or tissues with altered biological characteristics to achieve the desired medical outcome.

Tissue-Engineered Medicinal Products - Contain modified cells or tissues engineered to repair, regenerate, or replace human tissue structures.

EVOLVING REGULATORY LANDSCAPE

The European Medicines Agency (EMA) is currently updating its Good Manufacturing Practice (GMP) guidelines specific to ATMPs, which were originally issued as Eudralex Volume 4 Part IV (2017). The revised draft is expected in September 2026, with full implementation targeted for March 2027.

The update aims to:

- Align ATMP manufacturing with EU GMP Annex 1.
- Strengthen Quality Risk Management (QRM) and the Contamination Control Strategy (CCS).
- Integrate advancements in technology and best practices.

MICRONCLEAN SUPPORT FOR ATMP MANUFACTURING

While the regulatory framework is evolving, the core principles will remain unchanged, and this is where Micronclean's cleanroom products and knowledge can continue to deliver essential value. As most ATMPs cannot undergo terminal sterilisation and are typically manufactured in small batches, this means using stringent contamination control to maintain a highly controlled aseptic environment, usually within an isolator or RAB. This means using:

- ✓ Validated detergents and disinfectants that demonstrate efficacy against bacterial spores and relevant microorganisms.
- ✓ Proven disinfectant rotation protocols to mitigate microbial resistance.
- ✓ Cleaning schedules that are risk-based, process-specific and designed to prevent any residue build-up.
- ✓ Sterile detergents, disinfectants and cleaning materials in Grade A and B areas.

With decades of experience supporting advanced manufacturing environments, Micronclean should be your trusted ATMP contamination control partner. Not only can we supply all the products you need, but we also provide technical expertise through our in-house Technical Function, along with proven templates to help you define your Contamination Control Strategy

ALCOHOLS

For the ATMP market, all our IPA and IMS products are supplied sterile and blended to 70% alcohol by volume using Water for Injection (WFI) quality water. Additionally, we recommend that you use either a trigger spray and dry wipe or perhaps more conveniently our pre-saturated wipes. These are available in sessional wipe packs of 15 wipes which are ideal for small scale manufacturing and reduced waste.



Family	Product Code	Description	Size	Pack Qty	Case Qty
CleanGuard 1	ZSAL64499	IPA 500ml Trigger Spray Sterile	500ml	24	24 x 500ml
CleanGuard 1	ZSAL64950	IPA 950ml Trigger Spray Sterile	950ml	15	15 x 950ml
CleanGuard 2	ZSAL65499	IMS 500ml Trigger Spray Sterile	500ml	24	24 x 500ml
CleanGuard 2	ZSAL65950	IMS 950ml Trigger Spray Sterile	950ml	15	15 x 950ml
VeriGuard 2	WSCW92009	IPA Sessional Polycellulose C-folded Pouch Wipes Sterile	230x230mm	15	40 packs of 15
VeriGuard 2	WSCW91009	IMS Sessional Polycellulose C-folded Pouch Wipes Sterile	230x230mm	15	40 packs of 15
VeriGuard 3	WSVG06030	IPA Sessional Polyester V-folded Pouch Wipe Sterile	300x300mm	30	30 packs of 15
VeriGuard 3	MCZSLA50S	IPA Polyester Laundered Non-folded Pouch Wipes Sterile	300x300mm	50	5 packs of 50

The above product table does not show the regional product codes for clarity. However, to ensure that product labels with the correct languages are ordered and dispatched please contact us.

Family	Product Code	Description	Size	Pack Qty	Case Qty
CleanGuard 4	ZSAP01500	Alpha 500ml Trigger Spray Sterile	500ml	6	6 x 500ml
CleanGuard 3	ZSBT02500	Beta 500ml Tigger Spray Sterile	500ml	6	5 x 500ml
CleanGuard 5	ZSND05950	Delta 950ml Trigger Spray Sterile	950ml	15	15 x 950ml
VeriGuard 2	WSAP01009	Alpha Sessional Polycellulose C-folded Pouch Wipe Sterile	230x230mm	15	10 packs of 15
VeriGuard 2	WSBT02009	Beta Sessional Polycellulose C-folded Pouch Wipe Sterile	230x230mm	15	10 packs of 15
VeriGuard 2	WSND05009	Delta Sessional Polycellulose C-folded Pouch Wipe Sterile	230x230mm	15	10 packs of 15

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DETERGENTS AND DISINFECTANTS

Micronclean has developed Delta, a sterile neutral detergent to remove surface contamination from hard surfaces. This should be followed by either Alpha or Beta - sterile rotational hard surface disinfectants with different modes of action – to help prevent long-term resistance build-up. For all ATMP applications we recommend that you use either a trigger spray and dry wipe or perhaps more conveniently our pre-saturated wipes which are available in packs of 15 to minimise waste.



DRY WIPES AND ISOLATOR TOOLS

In all higher-grade cleanroom environments, especially RABS and LAFs, we recommend using polyester wipes as the default dry wipe, as they inherently generate fewer particles than the equivalent dry polycellulose wipe.

For improved practicality in ATMP applications, Micronclean can offer its PureGuard isolator system, which comprises a stainless-steel isolator cleaning tool and dual-layer sterile polyester bonnets. The cleaning tool is available with two different handle lengths to suit different cabinets sizes, while the bonnet is a universal fit and fits directly onto the cleaning tool improving your reach and cleaning ability.



Family	Product Code	Description	Size	Pack Qty	Case Qty
WhiteGuard 3	WSDPE5010	Polyester Laundered Non-Folded Wipe Sterile	300x300mm	50	10 packs of 50
WhiteGuard 3	MCDELN50S	Polyester Laundered Single Layer Non-Folded Wipe Sterile	300x300mm	50	10 packs of 50
WhiteGuard 11	MHPELN50S	Dual Layer Polyester Laundered Non-folded Wipe Sterile	300x300mm	50	4 packs of 50
PureGuard 6	ISEDRO140	Dry Dual Layer Polyester Laundered Isolator Bonnet Sterile	One Size	Each	40 packs of 1
PureGuard 7	ZNSS01035	Stainless Steel Isolator Cleaning Tool 35cm Non-Sterile	One Size	One Size	One
PureGuard 7	ZNSS01061	Stainless Steel Isolator Cleaning Tool 61cm Non-Sterile	One Size	One Size	One

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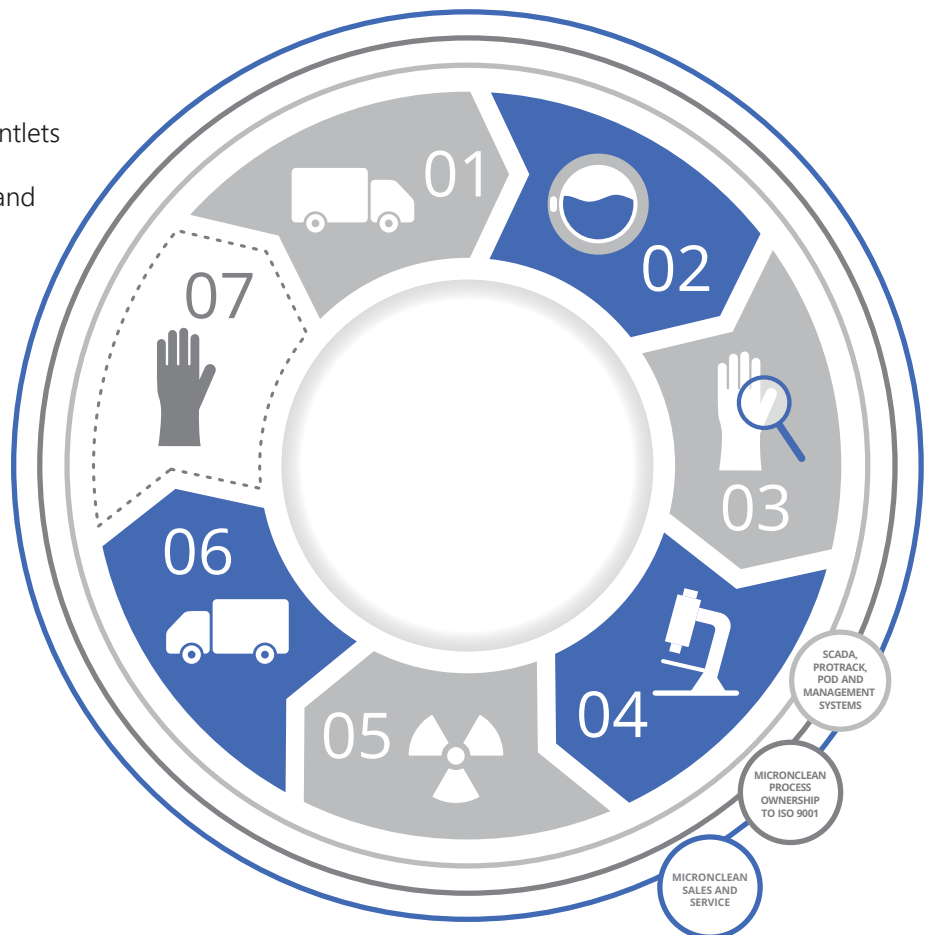
GAUNTLET SERVICE

Micronclean's Gauntlet Washing service, with optional pressure decay testing, provides a safe and effective way to extend gauntlet lifespan. The number of wash cycles depends on the material for instance, our standard EPDM gauntlets can typically be washed up to 10 times significantly increasing their usable life and helping to reduce overall costs.

Please note, this service is only available for gauntlets purchased from Micronclean.

GAUNTLET PROCESSING STAGES

01. Collection of Used Cleanroom Gauntlets
02. Cleanroom Gauntlets are washed and dried in an ISO GMP 4/Grade B facility
03. Inspection and scanning in
04. Optional Gauntlet Testing
05. Irradiation
06. Transported to your site
07. Ready for you to use



OPTIONAL GAUNTLET TESTING

Micronclean is unique in offering an integrated Gauntlet testing service which performs a pressure decay test on each gauntlet after decontamination and drying to ensure it is free from pinholes and tears. This means you can not only extend the Gauntlets life but also have confidence that every time it returns to your site it is proven to be fit for purpose.



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 **micronclean**
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