

Introduction to Redditch Medical

Redditch Medical's **InSpec**® products are manufactured in our Sedgefield site in County Durham. This site is located within the NETPark Discovery 2 Building, a new technology centre for the manufacture of GMP Pharmaceutical products. Situated a short drive from Newcastle Airport, major rail routes and the A1M. NETPark has strong links with the University of Durham and the local innovation community.

On the 2,000m² site we have two ISO 6 Cleanroom facilities of 80m² and 100m². These are purpose-built and dedicated to biocide manufacture and have been designed with good process flow and critical product manufacture in mind.

There are EN ISO Class 5 localised air shower facilities located within an ISO 6 environment for critical liquid filling and contract packing for pharmaceutical and medical device industries.

The facility also has a dedicated ATEX blending room, preparation areas and houses a WFI quality water system (Water for Injection) enabling high volume production of 1Ltr, 5Ltr, 500ml, 100ml and burstable wipes - both sterile and non-sterile variants.





Contents







Section 1 - Biocides

- Biocide mode of action
- Efficacy
- Rotation
- Cleaning Ability

Section 2 - How to mop a GMP cleanroom

- 3 bucket system
- Burstable mop system
- Mopping technique
- Product formats associated with mopping
 - InSpec® 5L Ready to use
 - **InSpec**® Concentrates

Section 3 - How to wipe surfaces in GMP environments

- Spray/wipe technique
- How to use Burstable Wipes
- Product formats associated with spraying and wiping
 - InSpec® Trigger sprays
 - InSpec® Dry Wipes
 - InSpec® Impregnated wipes
 - InSpec® Burstable wipes
- Trigger spray technology

Section 4 - Technical data summary of InSpec Products

- Alcohols **InSpec**® IPA & DE
- Disinfectants **InSpec**® QT, QT+ and AN
- Sporicides **InSpec**® HPX, OX and HA
- Cleaning detergents **InSpec**® N10 and N7

InSpec® Biocides Modes of Action

Redditch Medical has a comprehensive range of disinfectants and sporicides - it is important to understand the 'mode of action' of each chemistry.

InSpec* **IPA** - Isopropyl Alcohol & Denatured Alcohol (TSDA 7)

Role: Disinfectant Mode of action: denaturation of proteins

Alcohols are most effective when combined with water which facilitates diffusion through the cell membrane; 100% alcohol typically denatures only external membrane proteins. A mixture of 70% ethanol or isopropanol v/v diluted in water is more effective in denaturing protein and is effective against a wide spectrum of bacteria and fungi. InSpec® IPA and InSpec DE - Isopropyl alcohol and Denatured alcohol.

InSpec® HPX - Hydrogen peroxide with surfactant Role: Disinfectant/sporicide & cleaner Mode of action: oxidation of cellular components

Hydrogen peroxide produces destructive hydroxyl free radicals that attack membrane lipids, DNA, and other essential cell components. Hydrogen peroxide decays to water and oxygen. The provision of surfactants in HPX adds both cleaning ability and reduces the surface tension of the solution aiding contact and penetration.

InSpec® OX - Hydrogen peroxide with Peracetic acid Role: Disinfectant/sporicide Mode of action: oxidation of cellular components

It is well understood that in combination Hydrogen peroxide and Peracetic acid act synergistically to significantly improve bactericidal and sporicidal activity relative to those of either agent used separately.

InSpec® QT & QT+ -Quaternary ammonium compound Role: Disinfectant & cleaner Mode of action: inactivation of enzymes, denaturation

of enzymes, denaturation of cellular proteins & disruption of the cell membrane.

Quaternary ammonium compounds are cationic

Quaternary ammonium compounds are cationic detergents, as well as disinfectants which assists in cleaning ability and enhances contact with micro-organisms. QT+ has additional sequestrants improving the activity of the quaternary ammonium compounds allowing the concentration to be reduced whilst maintaining the same performance so reducing residue levels.

InSpec® AN - Diamine
Role: Disinfectant & cleaner
Mode of action: increases
the permeability of the
bacterial cell membrane,
leading to osmotic
imbalance / loss of amino
acids leading to cell
inactivation.

To enhance penetration and provide a cleaning ability surfactants are added to InSpec AN. Diamines are characterized by relatively low toxicity to mammals at ready to use concentrations. Consequently they are low hazard not normally attracting any hazard warning.

InSpec[®] **HA** - Hypochlorous Acid

Role: Disinfectant/sporicide Mode of action: oxidation of cellular components

Hypochlorous acid is a very powerful oxidant; hence is a very potent sporicide at low concentrations.
Hypochlorous acid reacts with proteins of many types denaturing and deactivating the protein's functionality.
Cellular components such as ribosomes, DNA, RNA, enzymes and structural proteins are all affected and destroyed.
The oxidation mechanism of Hypochlorous acid consists of electron transfer.

InSpec® Biocides Efficacy

Establishing the efficacy of a biocide is critical to selection of the correct programme of use within any cleanroom facility.

Qualification of the efficacy of the **InSpec**® range is achieved via European Standards - CEN TC 216 phase 1 & phase 2 (suspension tests and surface tests). Testing was performed by accredited 3rd party laboratories.



Summary of InSpec Biocide Qualification

Requirement of EN Standard & Performance of InSpec Product	EN 1276: Bacterial Suspension test	EN 1650: Fungal Suspension test	EN 13697: Bacterial Surface test	EN 13697: Fungal Surface test	EN 13704: Sporicidal Suspension Test	EN 14476: Virucidal Suspension Test
Organisms referenced	P. aeruginosa	C. albicans	P. aeruginosa	C. albicans	B. subtilis	Poliovirus-1,
by standard	S. aureus	A. brasiliensis	S. aureus	A. brasiliensis		Adenovirus-5
	E. hirae		E. hirae			Murine norovirus
	E. coli		E. coli			
Temperature				20°C		
Clean conditions			0.3 g/l	bovine albumin		
EN Contact time Required	5 mins	15 mins	5 mins	15 mins	60 mins	5 mins
EN Log Reduction Required	5 Log	4 Log	4 Log	3 Log	3 Log	4 Log
Achieved by InSpec QT	Pass	Pass	Pass	Pass	N/A	N/A
Achieved by InSpec QT+	Pass	Pass	Pass	Pass	N/A	N/A
Achieved by InSpec AN	Pass	Pass	Pass	Pass	N/A	N/A
Achieved by InSpec IPA	Pass	Pass	Pass	Pass	N/A	N/A
Achieved by InSpec DE	Pass	Pass	Pass	Pass	N/A	N/A
Achieved by InSpec HPX	Pass	Pass	Pass	Pass	Pass	N/A
Achieved by InSpec OX	Pass	Pass	Pass	Pass	Pass	N/A
Achieved by InSpec HA	Pass	Pass	Pass	Pass	Pass at 1 min	Poliovirus-1, > 4 log (Pa
						Adenovirus-5, 2.85 Log
						Murine norovirus, 1 Log

United States Pharmacopoeia (USP) General Chapter 1072 "Disinfectants and Antiseptics" 13.
This chapter stipulates that a 3 log reduction in the viable microbial count should be demonstrated for bacteria.

InSpec® Biocides Rotation

There are no hard and fast rules that define how frequently products are rotated **OR** how many disinfectants are rotated Rotational controls should be considered and results demonstrated.

It is up to the end user to decide upon a rotational programme and undertake validation of this and validate their own process.

A Rotational Programme should be based upon:

- Historic Environmental Monitoring (EM) data
- The periodic use of sporicides
- The results of efficacy studies
- On-going trended micro data

Noting:

- Alcohols are not normally included in the rotational programme, but can be used for periodic rinses to remove residues.
- Two or three disinfectants to be rotated - most use two - different modes of action to be taken into account.

Rotation can be used to combat other issues

- Corrosion
- H&S issues
- Cost
- Residue



High level disinfectant paired with another high level disinfectant

High level disinfectant paired with sporicide

Cleaning Ability

The cleaning ability of a biocide formulation can reduce cleaning times significantly dependent upon the soiling type and amount of soil to be dealt with.

Building this ability into the formulation is therefore important. Some biocides such as alcohols have no surfactant present and cleaning is dominated by a single mechanism – solubility.

The fact that alcohols have a lower surface tension also assists in removing soils. Those **InSpec**® products with surfactants present have addition cleaning mechanisms:

Wetting

Low surface tension allowing penetration behind soils and into cracks

Emulsification

Forming an emulsion of hydrophobic materials such as grease/oil into solution

Hydrolysis

Breaking down insoluble molecules rendering them more soluble

Solubility

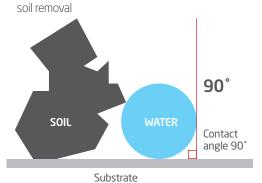
The Polarity of solvent molecules and soil compounds can either be polar or nonpolar. As a generality 'like dissolves like' i.e. polar soil dissolves in polar solvent; nonpolar soil dissolves in nonpolar solvent.

Summary of the Mechanisms at work in the InSpec Range

Efficacy				
InSpec Product	Surfactant Present	Туре	Dominant Cleaning Mechanism(s)	Cleaning Ability
InSpec IPA	No	N/A	Solubility	Medium
InSpec DE	No	N/A	Solubility	Medium
InSpec QT	Yes	Cationic Surfactant	Wetting + Emulsification + Solubility	High
InSpec QT+	Yes	Cationic Surfactant	Wetting + Emulsification + Solubility	High
InSpec AN	Yes	Anionic Surfactant	Wetting + Emulsification + Solubility	High
InSpec HPX	Yes	Non-Ionic	Wetting + Emulsification + Solubility	Medium
InSpec OX	No	N/A	Solubility	Medium
InSpec HA	No	N/A	Solubility	Medium
InSpec N7	Yes	Non-Ionic	Wetting + Emulsification + Solubility	High
InSpec N10	Yes	Non-Ionic	Wetting + Emulsification + Hydrolysis + Solubility	Very High

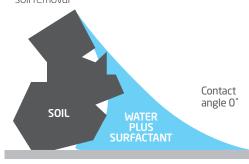
No Surfactant Present

- Surface tension is high
- Reduced probability of



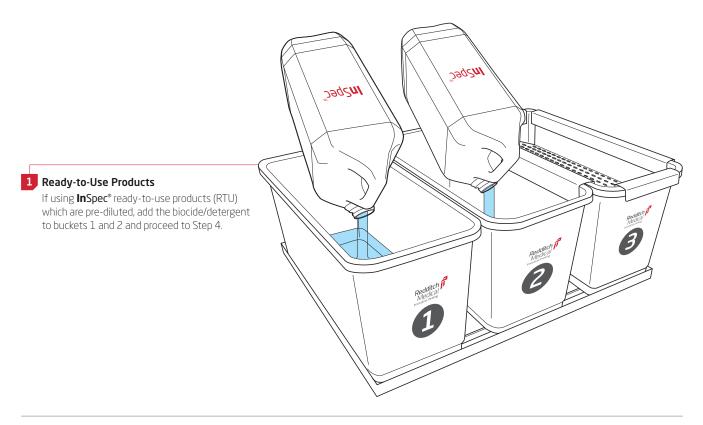
Surfactant Present

- Surface tension is reduced
- Enhanced probability of soil removal



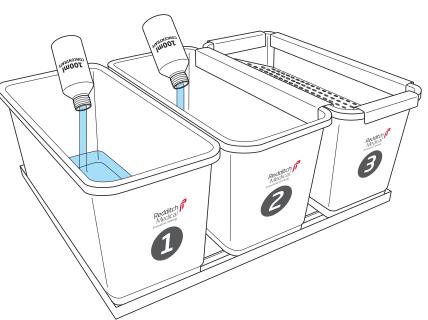
Substrate

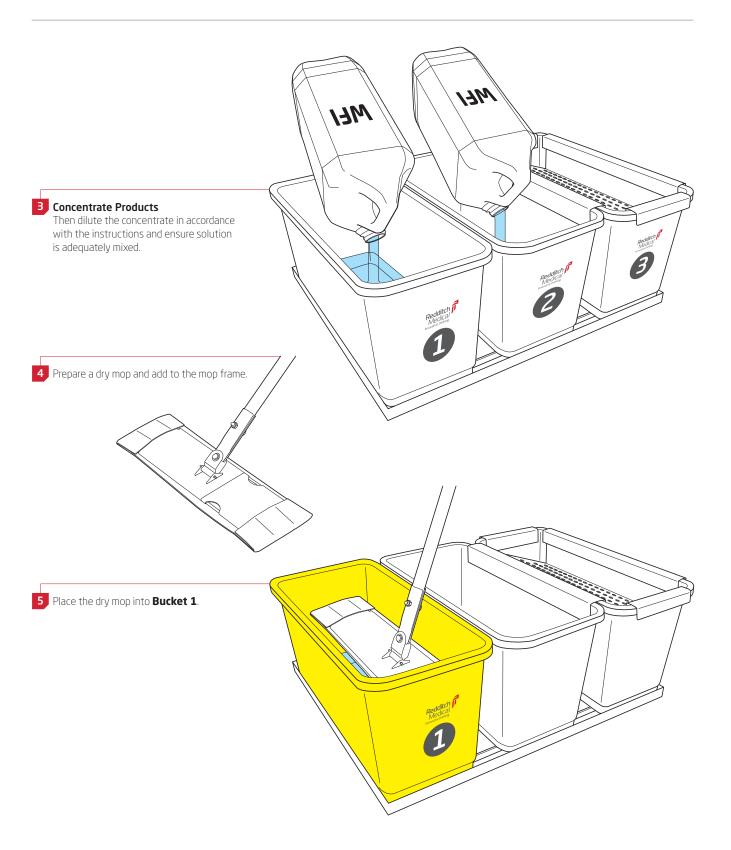
Preparation of Mops - 3 Bucket System

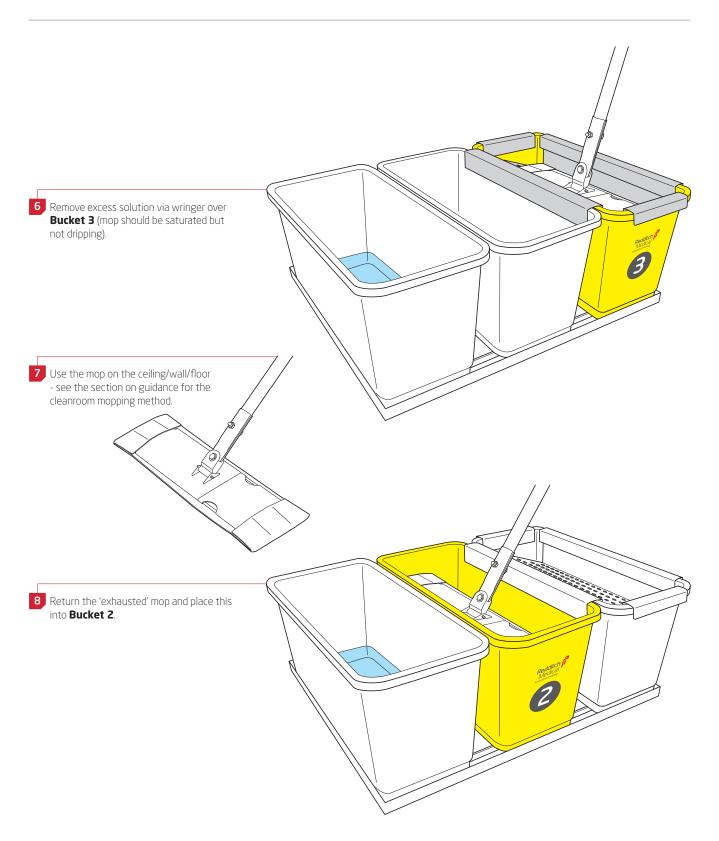


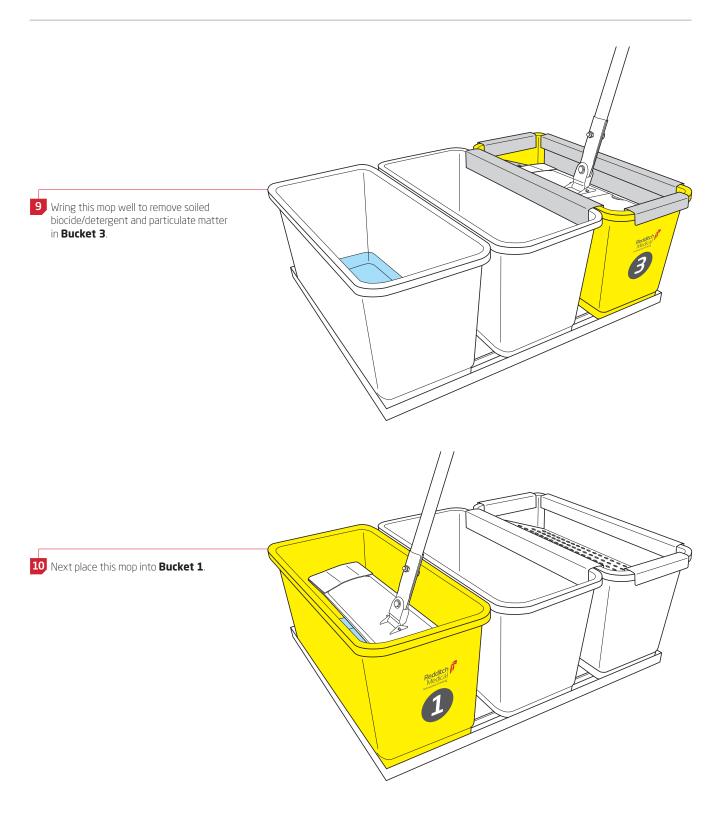
2 Concentrate Products

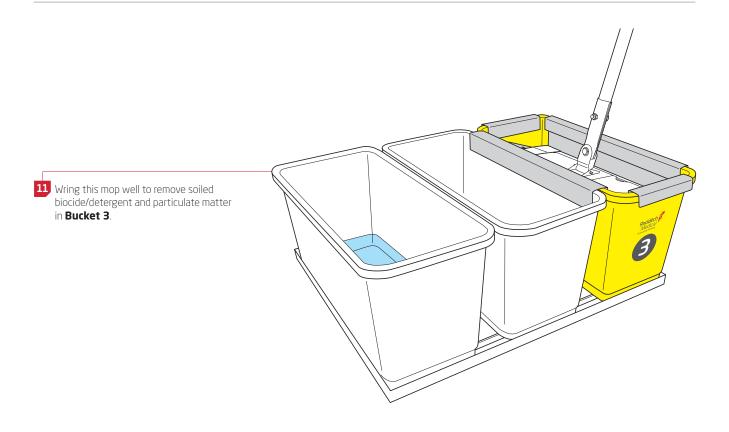
If using **InSpec*** concentrates - first add concentrated biocide / detergent to buckets 1 and 2.

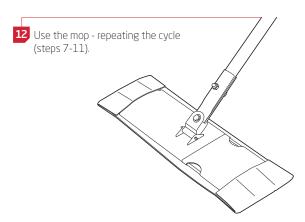






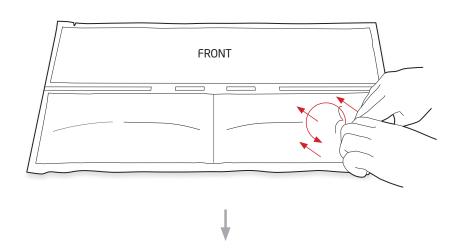




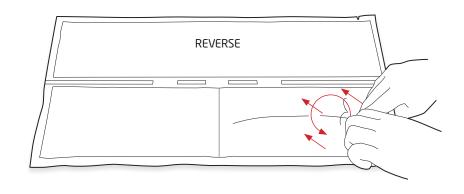


Preparation of Mops - Burstable System

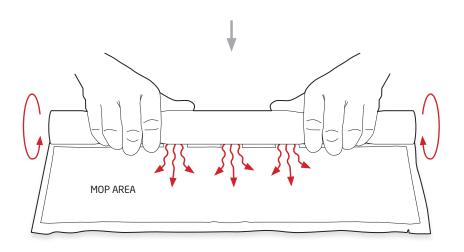
Place pouch on flat surface and roll the right hand liquid chamber then whilst holding it tight with one hand press down with the other hand to burst inner pouch #1. Squeeze out contents.



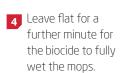
Turn over pouch - so the reverse side faces you and then roll the remaining right hand liquid chamber then whilst holding it tight with one hand press down with the other hand to burst inner pouch #2. Squeeze out contents.

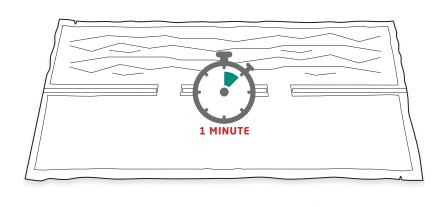


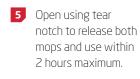
To ensure maximum flow of the biocide through to the mop side, roll and compress the liquid side of the pouch to force all liquid into the mop chamber.

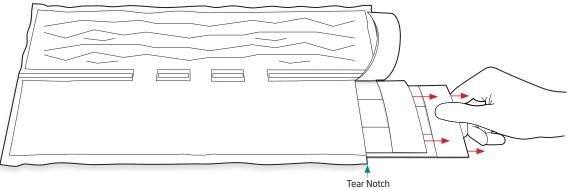


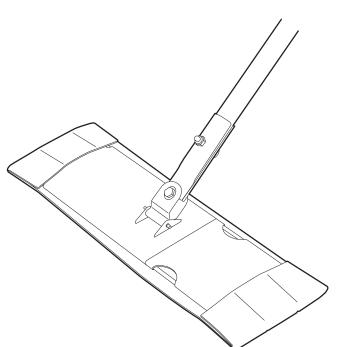
Preparation of Mops - Burstable System





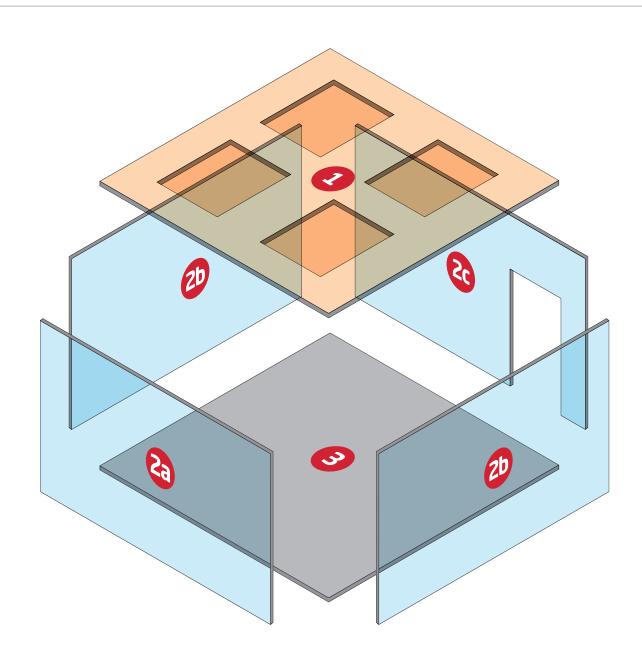






6 Attach the mop to the head and it is ready for use.

How to Mop a GMP Cleanroom



CLEANING ISO 5 AND ISO 6 CLEANROOMS

The sequence to follow when cleaning is:

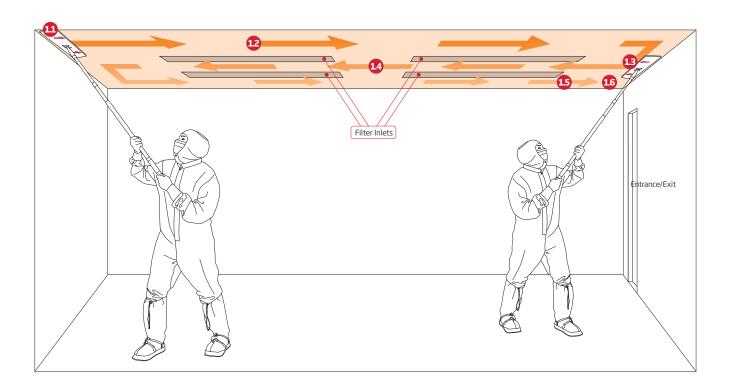
- 1 HEPA Filtered Ceiling
- 2 Walls in the sequence 23 20 20
- B Floor

Mopping Technique - Ceilings

1 HEPA FILTERED CEILING

The sequence to follow when cleaning the ceiling is:

- 4 Start with the impregnated mop in the top corner, typically furthest from the entrance/exit
- Wipe the mop straight across the surface
- 4 At the end, transition the mop to maintain the same leading edge
- Wipe the mop across the surface with a 10% overlap of the previous pass
- **4** Continue until the entire surface has been cleaned/disinfected up to 20m² per mop.
- Discard mop(s)

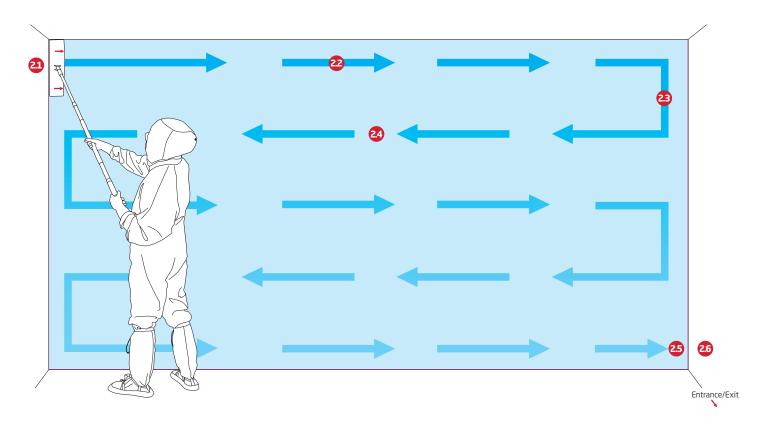


Mopping Technique - Walls

WALLS

The sequence to follow when cleaning walls is:

- Start with the impregnated mop in the top corner of the cleanest wall, typically furthest from the entrance/exit
- Wipe the mop straight across the wall surface
- At the end, transition the mop to maintain the same leading edge
- 4 Wipe the mop across the tent wall surface with a 10% overlap of the previous pass
- **3** Continue until the entire wall surface has been cleaned/disinfected up to 20m² per mop.
- Discard mop(s)

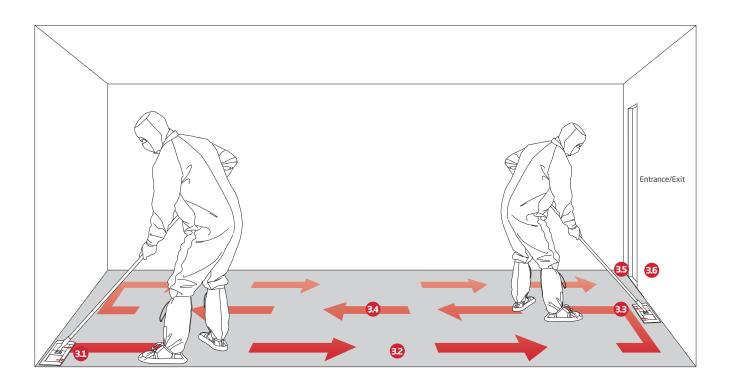


Mopping Technique - Floors

1 FLOORS

The sequence to follow when cleaning floors is:

- Start with the impregnated mop in the corner, typically furthest from the entrance/exit
- Wipe the mop straight across the floor surface
- 3 At the end, transition the mop to maintain the same leading edge
- 4 Wipe the mop across the floor surface with a 10% overlap of the previous pass
- 65 Continue working towards the most soiled area, typically the exit/entrance, until the entire floor surface has been cleaned/disinfected up to 20m² per mop.
- 35 Discard mop(s)



Product Formats Associated with Mopping

InSpec Range

5L Products Part Numbers

InSpec® Sterile 5L Products				
5L Product	Sterile 5L Part No.	No. per case		
InSpec QT	QTWFI30-5LS	2		
InSpec QT+	QTPLWFI31-5LS	2		
InSpec AN	ANWFI20-5LS	2		
InSpec IPA	IPAWFI1-5LS	2		
InSpec DE	DEWFI10-5LS	2		
InSpec HPX	HPXWFI160-5LS	2		
InSpec OX	OXPW40-5LS	2		
InSpec HA	HAPW50-5LS	2		
InSpec N7	N7WFI1-5LS	2		
InSpec N10	N10WFI1-5LS	2		

InSpec® Non-Sterile 5L Products				
Non-Sterile 5L Part No	No. per case			
NSQTWFI-5L	2			
NSQTPLWFI-5L	2			
NSANWFI-5L	2			
NSIPAWFI-5L	2			
NSDEWFI-5L	2			
N/A	N/A			
NSOXPW-5L	2			
NSHAPW-5L	2			
NSN7WFI-5L	2			
NSN10WFI-5L	2			

If a product option is designated as N/A this means Redditch Medical does not manufacture or stock this combination. However, if this is a product you require, please contact us to explore technical and commercial feasibility.

InSpec Range

Concentrate Products Part Numbers

InSpec® Sterile Concentrate Products				
Concentrate Product	100ml/102ml Sterile Part No.	No. per case		
InSpec QT	QTCNC30-100	50		
InSpec QT+	QTPLCNC-102	50		
InSpec AN	ANCNC20-100	50		
InSpec IPA	N/A	N/A		
InSpec DE	N/A	N/A		
InSpec HPX	N/A	N/A		
InSpec OX	N/A	N/A		
InSpec HA	N/A	N/A		
InSpec N7	N7WFI1-100MLS	50		
InSpec N10	N10WFI1-100MLS	50		

InSpec® Non-Sterile Concentrate Products				
100ml/102ml Non-Sterile Part No.	No. per case			
NSQTCONC-100ML	50			
NSQTPLCONC-102	50			
NSANCONC-100ML	50			
N/A	N/A			
NSN7CONC-100ML	50			
NSN10CONC-100ML	50			

If a product option is designated as N/A this means Redditch Medical does not manufacture or stock this combination. However, if this is a product you require, please contact us to explore technical and commercial feasibility.

InSpec Range

InSpec/Hydroflex Burstable Mops Part Numbers

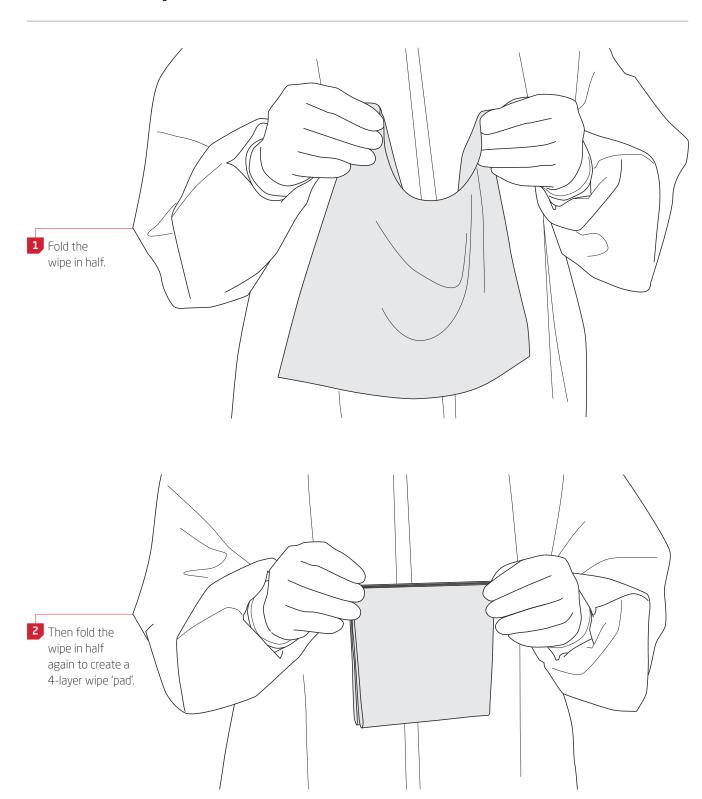
InSpec*/Hydroflex Sterile Burstable Mops							
InSpec Product	Burstable Mops 2 x EF40	No. per case	Burstable Mops 2 x EBF40	No. per case	Burstable Isolator Mops 2 x EC20	No. per case	
InSpec QT	2116008	5	N/A	N/A	N/A	N/A	
InSpec AN	2116006	5	N/A	N/A	N/A	N/A	
InSpec HPX	2116010	5	N/A	N/A	2116015	5	
InSpec OX	2116004	5	N/A	N/A	2116014	5	
InSpec HA	2116002	5	N/A	N/A	2116013	5	
InSpec N10	N/A	N/A	2116012	5	N/A	N/A	

InSpec N10	N/A	N/A	2116012	5	N/A	N/A
					nufacture or stock this d commercial feasibilit	



InSpec®/Hydroflex Non-Sterile Burstable Mops						
Burstable Mops 2 x EF40	No. per case	No. per case				
2116007	5	N/A	N/A			
2116005	5	N/A	N/A			
2116009	5	N/A	N/A			
2116003	5	N/A	N/A			
2116001	5	N/A	N/A			
N/A	N/A	2116011	5			

How to Wipe Surfaces in a GMP Environment



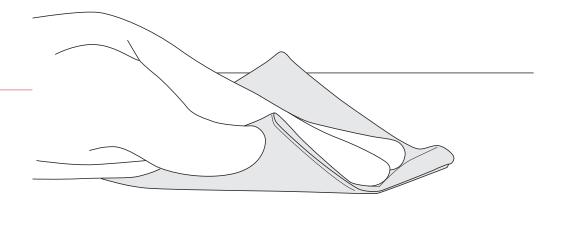
How to Wipe Surfaces in a GMP Environment



How to Wipe Surfaces in a GMP Environment

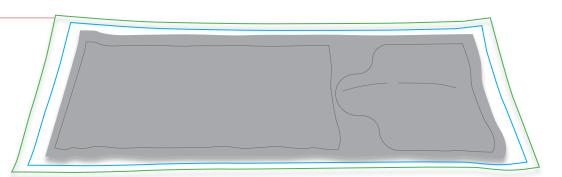


Continue to wipe the cleanroom surface using the folded edge of the wipe 'pad' as the leading edge.
Use 10% overlapping passes to ensure full coverage.

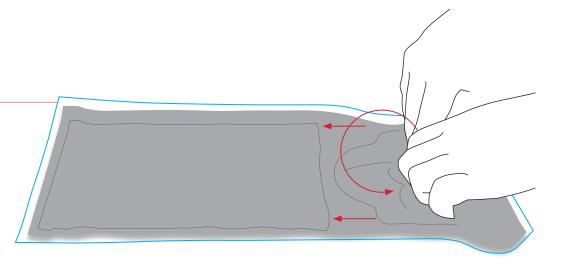


Use of Wipes - Burstable System

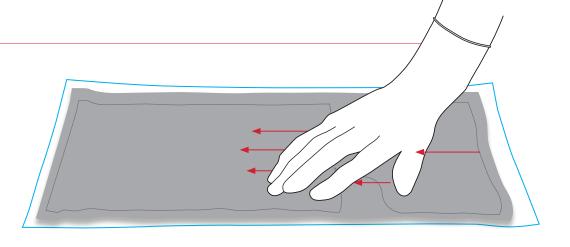
Ensure the pouch is free from defects and is placed on a hard flat surface. Remove all but one outer bag. NB – sterile products start with two outer bags, non-sterile versions only have a single outer bag.



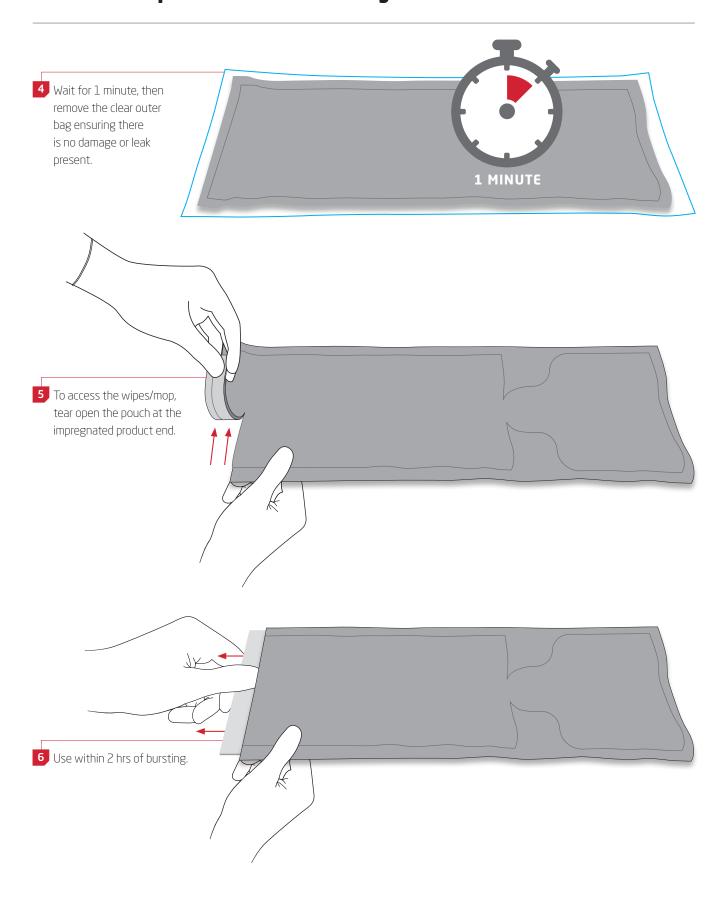
With a single outer bag remaining, roll the pouch from the liquid end and apply pressure to force the liquid across the frangible barrier to wet the wipes/mop.



Ensure liquid is fully transferred to the wipe/mop section.



Use of Wipes - Burstable System



Product Formats Associated with Spraying & Wiping

InSpec Range

Trigger Spray Part Numbers

InSpec® Ste	InSpec® Sterile Trigger Spray Products						InSpec® Non-	Sterile 1	Trigger Spray	Product	s	
Trigger Spray Product	Sterile 900ml Part No.	No. per case	Sterile 1 Litre Part No.	No. per case	Sterile 500ml Part No.	No. per case	Non-sterile 900ml Part No.	No. per case	Non-sterile 1 Litre Part No.	No. per case	Non-sterile 500ml Part No.	No. per case
InSpec QT	QTWFI30-1LS	6	N/A	N/A	N/A	N/A	NSQTWFI-1L	6	N/A	N/A	N/A	N/A
InSpec QT+	QTPLWFI31-900MLS	6	N/A	N/A	N/A	N/A	NSQTPLWFI-1L	6	N/A	N/A	N/A	N/A
InSpec AN	ANWFI20-1LS	6	N/A	N/A	N/A	N/A	NSANWFI-1L	6	N/A	N/A	N/A	N/A
InSpec IPA	N/A	N/A	IPAWFI1-1LS	6	IPAWFI-500MLS	8	N/A	N/A	NSIPAWFI-1L	6	NSIPAWFI-500ML	8
InSpec DE	N/A	N/A	DEWFI10-1LS	6	DEWFI11-500MLS	8	N/A	N/A	NSDEWFI-1L	6	NSDEWFI11-500ML	8
InSpec HPX	N/A	N/A	HPXWFI60-1LS	6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec OX	N/A	N/A	OXPW40-1LS	6	N/A	N/A	N/A	N/A	NSIOXPW-1L	6	N/A	N/A
InSpec HA	N/A	N/A	HAPW50-1LS	6	N/A	N/A	N/A	N/A	NSHAPW-1L	6	N/A	N/A
InSpec N7	N/A	N/A	N7WFICC-1LS	6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec N10	N/A	N/A	N10WFI1CC-1LS	6	N/A	N/A	N/A	N/A	NSN10WFI-1L	6	N/A	N/A

InSpec Range

Sterile Dry Wipes Part Numbers

InSpec* Sterile Dry Wipe Products						
Product	Sterile Part No.	No. per case	Wipe Media Type	Individual Wipe Size (mm)		
Dry Wipes 9" - 10 wipes/pack, 10 packs per bag	DW9X9S	10 (1,000 wipes in total)	Polycellulose 68 gsm	230 x 230		
Dry Wipes 12" - 10 wipes/pack, 10 packs per bag	DW12X12S	10 (1,000 wipes in total)	Polycellulose 68 gsm	300 x 300		
Dry Wipes 18" - 100 wipes per pack	DW18X18S	3 (300 wipes in total)	Polycellulose 68 gsm	450 x 450		

InSpec Range

Sterile Burstable Wipes Part Numbers

InSpec® Sterile Burstable Wipes					
Wipe Products	Burstable 15 Wipes	No. per case			
InSpec QT	QTWFI30BP15S	20			
InSpec QT+	QTPLWFI31BP15S	20			
InSpec AN	ANWFI20BP15S	20			
InSpec OX	OXPW40BP15S	20			
InSpec HA	HAPW50BP15S	20			



Product Formats Associated with Spraying & Wiping

InSpec Range

Sterile Wipes Part Numbers

InSpec® Ste	nSpec" Sterile Polycellulose Wipe Products									
Wipe Products	Individual Sachet Wipes	No. per case	Sterile Peel Back 15 Wipes	No. per case	Sterile Peel Back 50 Wipes	No. per case	Sterile Tub Wipe 200 per Roll	No. per case	Sterile Premium Tub Wipe 130 per Roll	No. per case
InSpec QT	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec QT+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec AN	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec IPA	IPAWFIPCH-1S	500	IPAWFIPCH15S	25	IPAWFIPCH50S	16	IPAWFI12TB200S	12	IPAWFI12TB130S	12
InSpec DE	N/A	N/A	DEWFIPCH15S	25	DEWFIPCH50S	16	DEWFI12TB200S	12	DEWFI12TB130S	12
InSpec HPX	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec OX	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec HA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
InSpec N7	N/A	N/A	N7WFIPCH15S	25	N7WFIPCH50S	16	N/A	N/A	N/A	N/A
InSpec N10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

InSpec® Non-Sterile Polycellulose Wipe Products							
Wipe Products	Non-Sterile Peel Back 15 Wipes	No. per case	Non-Sterile Peel Back 50 Wipes	No. per case	Non-Sterile Tub Wipe 200 per Roll	No. per case	
InSpec QT	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec QT+	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec AN	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec IPA	NSIPAWFIPCH15	25	NSIPAWFIPCH50	16	NSIPAWFI12TB200	12	
InSpec DE	NSDEWFIPCH15	25	NSDEWFIPCH50	16	NSDEWFI12TB200	12	
InSpec HPX	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec OX	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec HA	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec N7	N/A	N/A	N/A	N/A	N/A	N/A	
InSpec N10	N/A	N/A	N/A	N/A	N/A	N/A	

InSpec Range

Sterile Polyester Wipes Part Numbers

InSpec® Sterile IPA Polyester Wipes							
Wipe Products	Sterile Peel Back 15 Wipes 9"	No. per case	Sterile Peel Back 20 Wipes 12"	No. per case	Sterile Peel Back 30 Wipes 12"	No. per case	
InSpec IPA	IPAWFI15POL9	25	IPAWFI20P0L12	10	IPAWFI30POL12	10	







Trigger Spray Technology



Trigger Spray Technology

Inner collapsible liner

This liner enables the contents to be sprayed out without drawing air into the contents, maintaining sterility throughout use and is qualified for 3 months.



Technical Data of InSpec Products by Chemistry

Alcohol



Sterile Isopropyl Alcohol 70% v/v with WFI Quality Water

Rapid Action, Low Residue, Fast Drying Alcohol Disinfectant



InSpec* IPA is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping. Apply to surface to ensure complete coverage. For screw cap bottles use the entire contents after opening.

Technical Data

Appearance: Clear liquid free from particles. Specific Gravity (20°C): 0.872 to 0.883. Alcohol proportion: 70% +/- 2% v/v.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- Low residue
- Rapid action
- Bactericidal and Fungicidal
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-inbottle' presentation with Premium range
- Contents protected using filtered trigger presentation with standard range
- All formats manufactured with WFl quality water
- Multiple bags for cleanroom transfer
- Ideal surface and aseptic transfer disinfectants
- Manufactured in accordance with

Technical User Information

InSpec® IPA is a sterile ready to use disinfectant. This is a 70% v/v alcohol solution in WFI quality water.

InSpec® IPA is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process (at 25-45kGy) to give a sterility assurance level SAL of 10-6.

InSpec* IPA is supplied with Certificates of Conformity, Analysis and sterile versions also have certificates of Irradiation Sterility and Endotoxin. All formats of IPA have a stabilised 24 month shelf life.

Sachet Wipes

InSpec® IPA tear open sachets for single use wiping applications.

Pouch Wipes - Polycellulose

InSpec® IPA peel open pouch Wipes are high specification, low linting cleanroom wipes.

Tub Wipes

InSpec IPA Tub Wipes, an economical solution for wiping applications.

Pouch Wipes - Polyester

InSpec* IPA Knitted Polyester Wipes are high specification, laser cut, ultra low linting cleanroom wipes.

InSpec® IPA Sterile Products					
Product	Sterile Part No.	No. per case			
InSpec IPA 1L PREMIUM Trigger Spray	IPAWFI1-1LS	6			
InSpec IPA Triple Bagged Trigger Spray	IPAWFI3-1LS	6			
InSpec IPA 500ML PREMIUM Trigger Spray	IPAWFI-500MLS	8			
InSpec IPA 5L	IPAWFI1-5LS	2			
InSpec IPA 15 Pouch Wipes	IPAWFIPCH15S	25			
InSpec IPA 50 Pouch Wipes	IPAWFIPCH50S	16			
InSpec IPA Tub Wipes - 200 wipes/roll	IPAWFI12TB200S	12			
InSpec IPA PREMIUM Tub Wipes - 130 wipes/roll	IPAWFI12TB130S	12			
InSpec IPA Polyster 15 Wipes	IPAWFI15POL9	25			
InSpec IPA Polyster 20 Wipes	IPAWFI20P0L12	10			
InSpec IPA Polyster 30 Wipes	IPAWFI30POL12	10			
InSpec IPA Sachet - Individual Wipes	IPAWFIPCH-1S	10 x 50			

InSpec® IPA Non-Sterile Products			
Non-Sterile Part No.	No. per case		
NSIPAWFI-1L	6		
N/A	N/A		
NSIPAWFI-500ML	8		
NSIPAWFI-5L	2		
NSIPAWFIPCH15	25		
NSIPAWFIPCH50	16		
NSIPAWFI12TB200	12		
N/A	N/A		

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
Polycellulose 68gsm	230 x 230
Polycellulose 68gsm	230 x 230
Polycellulose 23gsm	200 x 200
Viscose 45gsm	200 x 185
Knitted Polyester	230 x230
Knitted Polyester	300 x 300
Knitted Polyester	300 x 300
Polycellulose 55 gsm	190 x 160

Technical Data of InSpec Products by Chemistry

Alcohol



Sterile Denatured Alcohol 70% v/v with WFI Quality Water

Rapid Action, Low Residue, Fast Drying Alcohol Disinfectant



InSpec* DE is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from wipe/area to be treated.

5L versions, pour all contents into an appropriate container for mopping. Apply to surface to ensure complete coverage. Wipes - access wipes via peel back opening, resealing as necessary. Sachets tear open.

Technical Data

Appearance: Clear liquid free from particles. Specific Gravity (20°C): 0.880 to 0.888. Denatured Ethanol proportion: 70% +/- 2% v/v.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- Low residue
- Rapid action
- Bactericidal and Fungicidal
- 1 Litre Trigger Spray has 3 months validated 'in-use' shelf life as contents are protected via 'bag-inbottle' technology
- All formats manufactured with WFI quality water
- Multiple bags for cleanroom transfer
- Ideal surface and aseptic transfer disinfectants
- Manufactured in accordance with GMP

Technical User Information InSpec® DE is a sterile ready to use disinfectant.

InSpec® DE Non-Sterile Products			
Non-Sterile Part No.	No. per case		
NSDEWFI-1L	6		
N/A	N/A		
NSDEWFI-500ML	8		
NSDEWFI-5L	2		
NSDEWFIPCH15	25		
NSDEWFIPCH50	16		
NSDEWFI12TB200	12		
N/A	N/A		

This is a 70% v/v denatured ethanol (TSDA 7) solution in WFI quality water.

InSpec* DE is manufactured in accordance with GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process (at 25-45kGy) to give a sterility assurance level SAL of 10-6.

InSpec* DE is supplied with Certificates of Conformity, Analysis and sterile versions also have certificates of Irradiation Sterility and Endotoxin. All formats of DE have a 24 month shelf life.

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
Polycellulose 68gsm	230 x 230
Polycellulose 68gsm	230 x 230
Polycellulose 23gsm	200 x 200
Viscose 45gsm	200 x 185

InSpec® DE Sterile Products				
Product	Sterile Part No.	No. per case		
InSpec DE 1L PREMIUM Trigger Spray	DEWFI10-1LS	6		
InSpec DE 1L JET Trigger Spray	DEWFI1-1JET	6		
InSpec DE 500ML PREMIUM Trigger Spray	DEWFI11-500MLS	8		
InSpec DE 5L	DEWFI10-5LS	2		
InSpec DE 15 Pouch Wipes	DEWFIPCH15S	25		
InSpec DE 50 Pouch Wipes	DEWFIPCH50S	16		
InSpec DE Tub Wipes - 200 wipes/roll	DEWFI12TB200S	12		
InSpec DE PREMIUM Tub Wipes - 130 wipes/roll	DEWFI12TB130S	12		

Technical Data of InSpec Products by Chemistry

Aqueous High Level Disinfectant



Sterile Diamine, Disinfectant Cleaner

Low Residue, Quat Free Disinfectant/Cleaner, Broad Spectrum Disinfectant



InSpec* AN is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping. 100ml concentrate added to 2.5L of water is required for mopping. Apply to surface to ensure complete coverage.

Technical Data

Alcohol, chlorine and QUAT-free disinfectant cleaner. 4% RTU Solution, pH 8.8-9.2, Concentrate pH 10.0.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- An exceptional non-oxidising biocide
- Bactericidal and Fungicidal
- Clean and disinfects
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-in-bottle' presentation with premium range
- 1L and 5L formats manufactured with WFI quality water
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec QT, HA and OX
- Manufactured in accordance with GMP

Technical User Information

InSpec* AN is a sterile disinfectant in pre-diluted and concentrated formats. InSpec* AN is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process (at 25-45kGy) to give a sterility assurance level SAL of 10^{-6} .

Trigger sprays supplied with 900ml solution in a 1L container.

InSpec* AN is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility. All formats of AN have a stabilised 24 month shelf life.

For screw cap bottles use the entire contents after opening.

InSpec* AN Sterile Products Product Sterile Part No. No. per case InSpec AN 900MLS PREMIUM ANWFI20-1LS 6 InSpec AN 5L ANWFI20-5LS 2 InSpec AN Concentrate ANCNC20-100 50 InSpec AN Burstable Pouch - 15 wipes ANWFI20BP15S 20

InSpec® AN Non-Sterile Products		
Non-Sterile Part No.	No. per case	
NSANWFI-1L	6	
NSANWFI-5L	2	
NSANCONC-100ML	50	
N/A	N/A	

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
N/A	N/A
N/A	N/A
Polycellulose 68gsm	230 x 230

Technical Data of InSpec Products by Chemistry

Aqueous High Level Disinfectant



Sterile Quaternary Ammonium Compound, Disinfectant Cleaner

Exceptional Quat disinfectant with proven efficacy against a wide range of Bacteria, Yeast and Fungi.



InSpec* QT is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping. 100ml concentrate added to 2.5L of water is required for mopping. Apply to surface to ensure complete coverage.

Technical Data

Aldehyde-free disinfectant cleaner. 4% RTU Solution pH 11.8-12.2 Concentrate pH 12.9.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- An exceptional non-oxidising biocide
- Bactericidal and Fungicidal
- Clean and disinfects in the presence of dirt, blood and proteins.
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-in-bottle' presentation with premium range
- 1L and 5L formats manufactured with WFI quality water
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec AN, HA and OX
- Manufactured in accordance with GMP

Technical User Information InSpec® QT is a sterile

disinfectant in pre-diluted and concentrated formats. InSpec* QT is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process (at 25-45kGy) to give a sterility assurance level SAL of 10-6.

Trigger sprays supplied with 900ml solution in a 1L container.

InSpec® QT is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility.

All formats of QT have a stabilised 24 month shelf life.

InSpec® QT Sterile Products				
Product	Sterile Part No.	No. per case		
InSpec QT 900MLS PREMIUM Trigger Spray	QTWFI30-1LS	6		
InSpec QT 5L	QTWFI30-5LS	2		
InSpec QT Concentrate	QTCNC30-100	50		
InSpec QT Burstable Pouch - 15 wipes	QTWFI30BP15S	20		
InSpec QT Burstable Mop - 2 EFB 40 Mops	2116008	5		

InSpec® QT Non-Sterile Products			
Non-Sterile Part No. No. per cas			
NSQTWFI-1L	6		
NSQTWFI-5L	2		
NSQTCONC-100ML	50		
N/A	5		
2116007	5		

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
N/A	N/A
N/A	N/A
Polycellulose 68 gsm	230 x 230
100% Polyester microfibre	400 x 100

Technical Data of InSpec Products by Chemistry

Aqueous High Level Disinfectant



Quaternary Ammonium Compound, Disinfectant Cleaner

Exceptional Quat disinfectant with proven efficacy against a wide range of Bacteria, Yeast and Fungi.



InSpec* QT+ is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping. 102ml concentrate make up to 5L with WFI Water. Apply to surface to ensure complete coverage.

Technical Data

Formulated Quaternary Ammonium Compound based disinfectant/cleaner. Active ingredient 0.12% RTU (ready to use). RTU pH = 10.5 to 11.5 Concentrate pH = 12.5 to 13.5.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical

Benefits

- An exceptional non-oxidising biocide
- Bactericidal and Fungicidal
- Low residue
- Contents protected using 'bagin-bottle' technology. Provides a validated 3 month 'in-use' shelf life.
- 1L and 5L formats manufactured with WFI quality water
- Double bagged to enable rapid cleanroom transfer
- Ideal rotational partner for InSpec AN, HA, OX and HPX products

Technical User Information InSpec* QT+ is available as a sterile or non-sterile disinfectant in prediluted and concentrated formats.

InSpec* QT+ is manufactured in accordance with GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and gamma irradiated via a validated process (at 25-45kGy) providing a sterility assurance level SAL of 10-6.

Trigger sprays supplied with 900ml solution in a 1L container.

InSpec* QT+ is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility. All formats of QT have a stabilised 24 month shelf life

InSpec® QT+ Sterile Products		
Product	Sterile Part No.	No. per case
InSpec QT+ 900mls Premium Trigger Spray	QTPLWFI31-900MLS	6
InSpec QT+ 5L	QTPLWFI31-5LS	2
InSpec QT+ Concentrate 102ml	QTPLCNC-102	50
InSpec QT+ Burstable Pouch Wipes - 15 wipes	QTPLWFI31BP15S	20

InSpec® QT+ Non-Sterile Products		
Non-Sterile Part No.	No. per case	
NSQTPLWFI-1L	6	
NSQTPLWFI-5L	2	
NSQTPLCONC-102	50	
N/A	N/A	

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A

Technical Data of InSpec Products by Chemistry

Aqueous Sporicidal Agents



Sterile Surface Preparation 7% Hydrogen Peroxide blended with 1% Diamine & Non-ionic Surfactants in Purified Water



InSpec* HPX is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping.

Technical Data

Appearance: Colourless, odourless, clear liquid. pH 2-3.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- One of the most common disinfectants available on the market
- Stabilised solution 12 months shelf life
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-inbottle' presentation with premium range.
- 1L and 5L and burstable wipes and mops formats available in Ready to Use dilution form.
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec QT and AN
- Manufactured in accordance with GMP

InSpec* HPX Non-Sterile Products			
Non-Sterile Part No.	No. per case		
N/A	N/A		
N/A	N/A		
2116009	5		

Technical User Information

InSpec* HPX is a sterile sporicide available ready to use.

InSpec* HPX is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and aseptically filled into pre-gamma irradiated packaging (25-45kGy) and tested to give a sterility assurance level SAL of 10⁻⁶.

InSpec® HPX is supplied with a certificate of conformity and analysis and sterility.

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
N/A	N/A
100% Polyester microfibre	400 x 100

InSpec® HPX Sterile Products			
Product	Sterile Part No.	No. per case	
InSpec HPX 1L PREMIUM Trigger Spray	HPXWFI160-1LS	6	
InSpec HPX 5L	HPXWFI160-5LS	2	
InSpec HPX Burstable Mop - 2 EF40 Mops	2116010	5	

Technical Data of InSpec Products by Chemistry

Aqueous Sporicidal Agents



Sterile Sporicidal Preparation Hydrogen Peroxide 6% v/v and Peracetic Acid 0.4% v/v

Rapid action - two minute kill time. Achieves the EN sporicidal standard - 3 log reduction in 2 minutes



Use Instructions

InSpec* 0X is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping.

Technical Data

Appearance: Colourless clear liquid with a characteristic strong acetic odour. pH 1.4.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- One of the most effective sporicides available on the market
- All formats classed as an irritant.
- Low Hazard
- Stabilised solution 24 months shelf life
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-in-bottle' presentation with premium range
- 1L and 5L formats available as Ready to Use
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec OT and AN
- Manufactured in accordance with GMP

Technical User Information

InSpec* OX is a sterile sporicide available ready to use.

InSpec* OX is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and aseptically filled into pre-gamma irradiated packaging (25-45kGy) and tested to give a sterility assurance level SAL of 10^{-6} .

InSpec* 0X is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility. All formats of OX have a stabilised 24 month shelf life.

erile Products		Wipe Media Type	Individual Wipe size	
	No. per case		(mm)	
	6	N/A	N/A	
	2	N/A	N/A	
	N/A	N/A	N/A	
	5	100% Polyester microfibre	400 x 100	

InSpec® OX Sterile Products			
Product	Sterile Part No.	No. per case	
InSpec OX 1L PREMIUM Trigger Spray	OXPW40-1LS	6	
InSpec OX 5L	OXPW40-5LS	2	
InSpec OX Burstable Pouch - 15 wipes	OXPW40BP15S	20	
InSpec OX Burstable Mop - 2 EF40 Mops	2116004	5	

InSpec® OX Non-Sterile Products		
Non-Sterile Part No.	No. per case	
NSIOXPW-1L	6	
NSOXPW-5L	2	
N/A	N/A	
2116003 5		

Technical Data of InSpec Products by Chemistry

Aqueous Sporicidal Agents

InSpec® HA

Sterile Sporicidal Preparation of Hypochlorous Acid (HC10 ≥ OCI + H+) Low odour, safe handling, low residue and fully effective



Use Instructions

InSpec* HA is designed for spraying, wiping and mopping applications. Hold spray approximately 15cm to 20cm from area to be treated. 5L versions, pour into an appropriate container for mopping.

Technical Data

Appearance: Colourless aqueous solution with a characteristic mild chlorine odour. pH 6.5 to 7.5.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Efficacy

See summary table in Section 1 of this brochure.

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- One of the safest and fully effective sporicides. All formats are non hazardous
- Very low residue, corrosion and odour
- Stabilised solution 12 months shelf life
- 3 months validated 'in-use' shelf life
- Contents protected using 'bag-inbottle' presentation with premium range.
- 1L and 5L formats available as Ready to Use
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec QT and AN
- Manufactured in accordance with GMP

Technical User Information

InSpec* HA is a ste sterile sporicide available ready to use.

InSpec* HA is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

The solution is filtered through a 0.2 micron filter and aseptically filled into pre-gamma irradiated packaging (25-45kGy) and tested to give a sterility assurance level SAL of 10⁻⁶.

InSpec™ HA is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility.

All formats of HA have a stabilised 12 month shelf life.

InSpec® HA Sterile Products		
Product	Sterile Part No.	No. per case
InSpec HA 1L PREMIUM Trigger Spray	HAPW50-1LS	6
InSpec HA 5L	HAPW50-5LS	2
InSpec HA Burstable Pouch - 15 wipes	HAPW50BP15S	20
InSpec HA Burstable Mop - 2 EFB 40 Mops	2116002	5

InSpec®HA Non-Sterile Products	
Non-Sterile Part No.	No. per case
NSHAPW-1L	6
NSHAPW-5L	2
N/A	N/A
2116001	5

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
N/A	N/A
Polycellulose 68 gsm	230 x 230
100% Polyester microfibre	400 x 100

InSpec®

Technical Data of InSpec Products by Chemistry

Aqueous Cleaning Detergents



Low Toxicology, pH Neutral Detergent Solution

Use Instructions

InSpec® N7 is designed for cleaning hard surfaces by spraying, wiping and mopping. Hold spray approximately 15cm to 20cm from the surface area. 5L versions, pour into an appropriate container for mopping. 100ml concentrate added to 2.5L of water is required for mopping. Apply to surface to ensure complete coverage.

Technical Data

N7 Ready to Use (RTU) is a 4% neutral detergent, pH7. The neutral detergent has surfactant and sequestering agents designed to assist the removal of process residue and light soiling in a cleanroom environment.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered. Compatibility information in the Technical Dossier.

Benefits

- Designed for cleaning floors, walls, ceiling and other hard surfaces for the removal of process derived residue and light soiling.
- Ideal for critical surfaces with soiling near to product manufacturing
- Very low foaming, low residue
- detergent with an excellent low toxicology profile
 Suitable for manual cleaning and available in convenient ready to use and concentrate formats.
- Low concentration
- 3 months validated 'in-use' shelf life
- All formats manufactured with WFl quality water
- Multiple bags for cleanroom transfer
- Manufactured in accordance with

Technical User Information

InSpec* N7 is available in sterile RTU pre-diluted formats and as a concentrate.

InSpec* N7 is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

RTU solutions are diluted with WFI quality water.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process to give a sterility assurance level SAL of 10-6.

InSpec® N7 is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility.

InSpec® N7 Sterile Products		
Product	Sterile Part No.	No. per case
InSpec N7 1L PREMIUM Trigger Spray	N7WFI1CC-1LS	6
InSpec N7 5L	N7WFI1-5LS	2
InSpec N7 Concentrate - 100ml	N7WFI1-100MLS	50
InSpec N7 Pre-impregnated Wipes x 15	N7WFIPCH15S	25
InSpec N7 Pre-impregnated Wipes x 50	N7WFIPCH50S	16

InSpec® N7 Non-Sterile Products	
Non-Sterile Part No.	No. per case
NSN7WFI-1L	6
NSN7WFI-5L	2
NSN7CONC-100ML	50
N/A	N/A
N/A	N/A

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A

InSpec®

Technical Data of InSpec Products by Chemistry

Aqueous Cleaning Detergents



Manual Detergent Pre-Diluted and Concentrate Solutions

An alkaline detergent and hard surface cleaner for use in the biopharmaceutical and cleanroom industries.



Use Instructions

InSpec* N10 is designed for cleaning hard surfaces by spraying, wiping and mopping. Hold spray approximately 15cm to 20cm from the surface area. 5L versions, pour into an appropriate container for mopping. 100ml concentrate added to 2.5L of water is required for mopping. Apply to surface to ensure complete coverage.

Technical Data

N10 Ready to Use (RTU) is a 4% alkaline detergent, pH12. The concentrate presentation has a pH of >13. The alkaline detergent has surfactant and sequestering agents designed to assist the removal of process residue and general soiling.

Storage & Safe Handling

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical Dossier.

Benefits

- Designed for cleaning floors, walls, ceiling and other hard surfaces for the removal of general process derived residue and soiling.
- Rapid action alkaline detergent.
 Suitable for manual cleaning.
- Available in convenient ready to use formats.
- 3 months validated 'in-use' shelf life
 1L and 5L formats manufactured with WFI quality water
- Multiple bags for cleanroom transfer
- Manufactured in accordance with GMP

Technical User Information

InSpec* N10 is available as a sterile and non-sterile detergent in prediluted and concentrated formats.
InSpec* N10 is manufactured to GMP in an ISO 6 cleanroom. The product is filled and capped in an ISO class 5 environment.

RTU solutions are diluted with WFI quality water.

The solution is filtered through a 0.2 micron filter and gamma irradiated to a validated process (at 25-45kGy) to give a sterility assurance level SAL of 10^{-6} .

InSpec® N10 is supplied with Certificates of Conformity, Analysis, Irradiation and Sterility.

InSpec® N10 Sterile Products		
Product	Sterile Part No.	No. per case
InSpec N10 900mls PREMIUM Trigger Spray	N10WFI1CC-1LS	6
InSpec N10 5L	N10WFI1-5LS	2
InSpec N10 Concentrate - 100ml	N10WFI1-100MLS	50
InSpec N10 Concentrate - 1L	N/A	N/A
InSpec N10 Burstable Mop - 2 EFB 40 Mops	2116012	5

InSpec® N10 Non-Sterile Products		
Non-Sterile Part No.	No. per case	
NSN10WFI-1L	6	
NSN10WFI-5L	2	
NSN10CONC-100ML	50	
NSN10CONC-1L	6	
2116011	5	

Wipe Media Type	Individual Wipe size (mm)
N/A	N/A
100% Polyester microfibre	400 x 100

Notes	

Notes	

Notes	

InTact® Solutions Delivered by Innovation

InTact® GMP Cleaning Detergents

CIP & COP Cleaning doesn't need to cost the earth

When Redditch Medical set out to design a new range of CIP and COP detergents for GMP use, our development was entirely focused on the pharmaceutical industry and the environment.

All **In**Tact® detergent formulations - Acid, Alkaline or Neutral - have the following characteristics:

- Biodegradable surfactants and chelants
- Manufactured in the UK to ISO 9001 & ISO 14001
- Releasable toxicology and formulation profiles
- Pre-qualified analytical detection methods -TOC and ICP-MS
- Rapid rinsing
- Range of size formats to cope with all application scales
- Low foaming
- Designed to work with DI/RO/Purified and WFI quality water

Redditch Medical's Optimisation Service

A free of charge laboratory-based service in which stainless steel or glass coupons representing an endusers actual drug and excipient soiling are tested in our laboratory to determine which cleaning agent should be used and under what parameters - time, action, concentration, and temperature - mimicking real world cleaning process conditions. This is why our product is called **In**Tact*.

The results from these studies assist by minimising the amount of product used and thus further reduce environmental impact. It additionally provides users with both a rationale behind product selection and an optimised starting point to move to field scale evaluation.





redditchmedical.com

InTact®

Solutions Delivered by Innovation

For more information about our InTact™ range of detergents, please contact: intact@redditchmedical.com or call us on +44 (0) 740 623379

Redditch Medical

Further Information

If you would like any further information about Redditch Medical, or would like to enquire about our products and services, please call our sales team via:

Tel: +44 (0) 1740 623379 E-mail: sales@redditchmedical.com

Or fill in the enquiry form on our website **www.redditchmedical.com**



Redditch Medical

Discovery 2 2 William Armstrong Way NETPark, Sedgefield Co Durham TS21 3FD UK



