

# Wipes

For cleanrooms and controlled environments





# Company Overview

#### Cleanroom Hygiene Innovations

Hydroflex is a leading supplier and manufacturer of cleanroom cleaning systems. Our specialized product solutions for manual cleaning and disinfection help control and eliminate particles and germs in cleanrooms every day – in over 40 countries worldwide. Under our established product brands PurMop® and PurWipe® we develop and distribute certified mop systems and wipes for all applications in cleanrooms and controlled environments. Thanks to our ongoing innovation and product development, a clear focus on comprehensive service and our certified quality management system, renowned companies from industries such as Pharmaceutical, Medical Devices, Microelectronics, Optics and many more rely on us. With our worldwide distribution network, established production sites and expert knowledge in cleanroom hygiene we are ready to support you.





#### Our brands







#### These industries rely on us













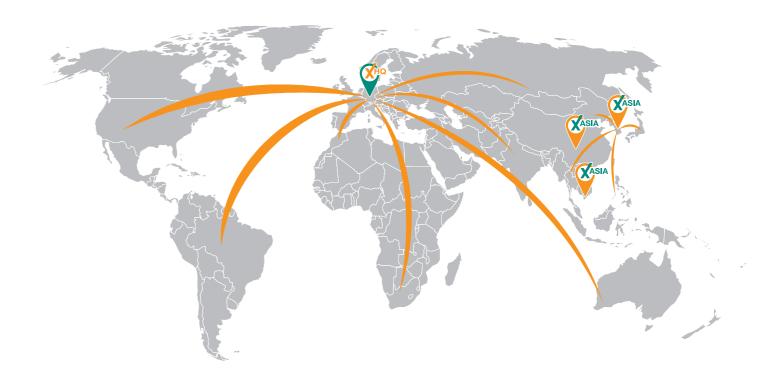
# The Hydroflex Group

#### Specialized solutions engineered in Germany – for cleanrooms worldwide

Hydroflex has recognized the dynamic development of the cleanroom market and the growing demand for specialized cleanroom cleaning systems. Today we are internationally set up to offer our global customers an optimal service.

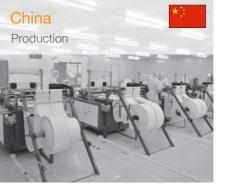
From the first idea through to the development, testing, and certification our products are engineered in Germany and are distributed worldwide through the Hydroflex Group. At our production sites in Asia, we manufacture our wiping textiles – cleanroom mops and wipes of our PurMop® and PurWipe® series – according to international standards and certified cleanroom procedures. Our cleaning equipment (trolleys, accessories, cleanroom vacuum cleaners) are manufactured according to our specifications in Germany, and can be flexibly adapted to your individual requirements.

Wherever you operate a cleanroom, a partner of our worldwide distribution network can advise you with specialist knowledge and introduce the optimal solution to clean your cleanroom.













# Nonwoven wipes

These cleanroom wipes consist of a special bonded nonwoven material and can be used in cleanrooms for various applications – from disinfection to absorbing liquids. They are designed for single use in lower class cleanrooms and for less critical applications. Nonwoven wipes boast a high fluid absorbency along with good price/performance ratio.

#### Features of our nonwoven wipes

- ▶ Consist of bonded staple fibers or spunbonded material
- ▶ Ensure good fluid absorption
- ▶ Have lower production cost
- Are not pre-washed

# PRODUCT IDENTIFICATION Edge N1-109-S Material Size Sterility

# Manufacturing process

#### PurWipe® cleanroom wipes

A combination of many years of experience, state-of-the-art cleanroom production, specially developed processing machines and a strict quality management system have enabled us to achieve the highest quality standards in our PurWipe® products. The high purity of our knitted cleanroom wipes is mainly due to the special manufacturing process that takes place in the cleanroom from the first step. This not only ensures lower particle emission, but also leads to a higher production efficiency. The comprehensive product tests for each production batch are performed by our in-house and independently certified laboratory and according to international standards. Therefore PurWipe® cleanroom wipes offer you the high level of safety that your cleanroom requires.

#### Below is an overview of the manufacturing steps of our N-Series:







**Cutting** of the raw material into wipes (cleanroom ISO 6)



**Inspection** of the raw material according to defined criteria



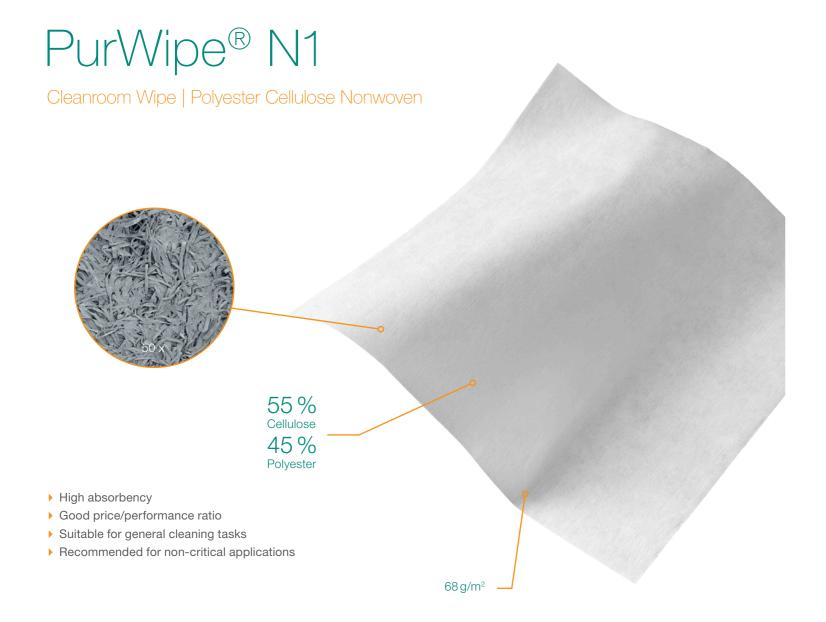
Tests and laboratory analysis of each batch before release



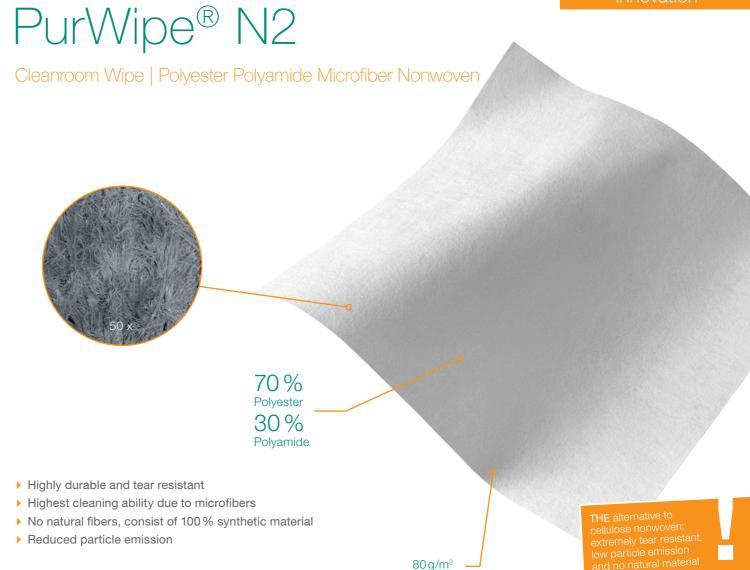
**Gamma sterilization** (if necessary) in an ISO 9001 certified factory



Inspection of incoming goods and storage (GMP warehouse)



PurWipe® N1 polyester cellulose nonwoven wipes consist of a high-quality, hydroentangled nonwoven material. Thanks to the superb fluid absorption capacity they are ideal for the disinfection of smooth surfaces and for absorbing larger volume of fluids. The bonded structure removes common dirt and makes the wipe ideal for general applications in cleanrooms with lower classification.



The new and innovative PurWipe® N2 cleanroom wipe consists of a polyester/polyamide microfiber nonwoven material. This robust material is manufactured by a special process utilizing only synthetic fibers. The ultrafine microfibers ensure good fluid absorbency as well as a high cleaning ability and optimal removal of tiny particles on all types of surfaces. Thanks to its superior tear resistance, the N2 wipe is well suited for use on stainless steel, on sharp-edged objects and for general cleaning and disinfection.

N1-109	N1-112	N1-109-S [STERILE]	N1-112-S [STERILE]
<ul><li>▶ Size: 23x23cm   9x9"</li><li>▶ Edges: Cut</li></ul>	➤ Size: 30x30cm   12x12"  ➤ Edges: Cut	<ul><li>▶ Size: 23x23cm   9x9"</li><li>▶ Edges: Cut</li></ul>	➤ Size: 30x30cm   12x12"  ➤ Edges: Cut
➤ Packaging: 300 pcs/bag (pack) 10 packs/case [3.000]  ➤ Item no.: 2183100	➤ Packaging: 300 pcs/bag (pack) 10 packs/case [3.000]  ➤ Item no.: 2183102	Packaging: 20 pcs/bag, 10 bags/pack, 10 packs/case [2.000]  ▶ Item no.: 2183101	➤ Packaging: 20 pcs/bag, 10 bags/pack, 10 packs/case [2.000] ➤ Item no.: 2183103
ISO GMP	3 4 5 6 7 8 A/B C D	1 ISO GMP	3 4 5 6 7 8 A/B C D

N2-109	N2-112	N2-109-S [STERILE]	N2-112-S [STERILE]
➤ Size: 23x23cm   9x9"  ➤ Edges: Cut	➤ Size: 30x30cm   12x12"  ➤ Edges: Cut	<ul><li>▶ Size: 23x23cm   9x9"</li><li>▶ Edges: Cut</li></ul>	➤ Size: 30x30cm   12x12"  ➤ Edges: Cut
Packaging: 100 pcs/bag (pack) 20 packs/case [2.000] ► Item no.: 2183500	<ul> <li>▶ Packaging: 100 pcs/bag (pack) 20 packs/case [2.000]</li> <li>▶ Item no.: 2183502</li> </ul>	<ul> <li>▶ Packaging:</li> <li>20 pcs/bag,</li> <li>10 bags/pack,</li> <li>10 packs/case [2.000]</li> <li>▶ Item no.: 2183501</li> </ul>	Packaging: 20 pcs/bag, 10 bags/pack, 10 packs/case [2.000]  ▶ Item no.: 2183503
1 ISO GMP	3 4 5 6 7 8 A/B C D	1 ISO GMP	3 4 5 6 7 8 A/B C D



# Knitted wipes

In any cleanroom, knitted wipes are the basis for an effective cleaning and disinfection process on sensitive and critical surfaces. They consist of synthetic fibers, are pre-washed and emit only low levels of particles. PurWipe® knitted wipes are available with different edge sealing options, as well as in various sizes and material weights, thus offering the right solution for every application.

#### Features of our knitted wipes

- ▶ Consist of continuous filaments
- ▶ Made from 100 % synthetic fibers
- ▶ Good chemical and mechanical resistance
- ▶ Pre-washed multiple times with ultrapure water
- ▶ Ensure consistently low particle emission
- ▶ Ideal for use in critical production areas

# PRODUCT IDENTIFICATION

# Manufacturing process

#### PurWipe® cleanroom wipes

A combination of many years of experience, state-of-the-art cleanroom production, specially developed processing machines and a strict quality management system have enabled us to achieve the highest quality standards in our PurWipe® products. The high purity of our knitted cleanroom wipes is mainly due to the special manufacturing process that takes place in the cleanroom from the first step. This not only ensures lower particle emission, but also leads to a higher production efficiency at the same time. The comprehensive product tests for each production batch are performed by our in-house and independantly certified laboratory and according to international standards. Therefore PurWipe® cleanroom wipes offer you the high level that your cleanroom requires.

#### Below is an overview of the manufacturing steps of our K-Series:



in cleanroom bags (cleanroom ISO 5)

Double packaging

Inspection and lab testing of each batch

ISO 9001-certified plant

(GMP-compliant)





The K1 polyester wipe is the basis of the knitted wipe range and is designed for a wide range of applications. It comprises of a high-quality double-knit material boasting good absorbency and durability. Due to its two-dimensional structure the K1 removes even tough residues and contaminants from surfaces of all kinds. The heatsealed edges along with the special decontamination process ensure very low particle emission, rendering the K1 suitable for even the most critical applications in cleanrooms.

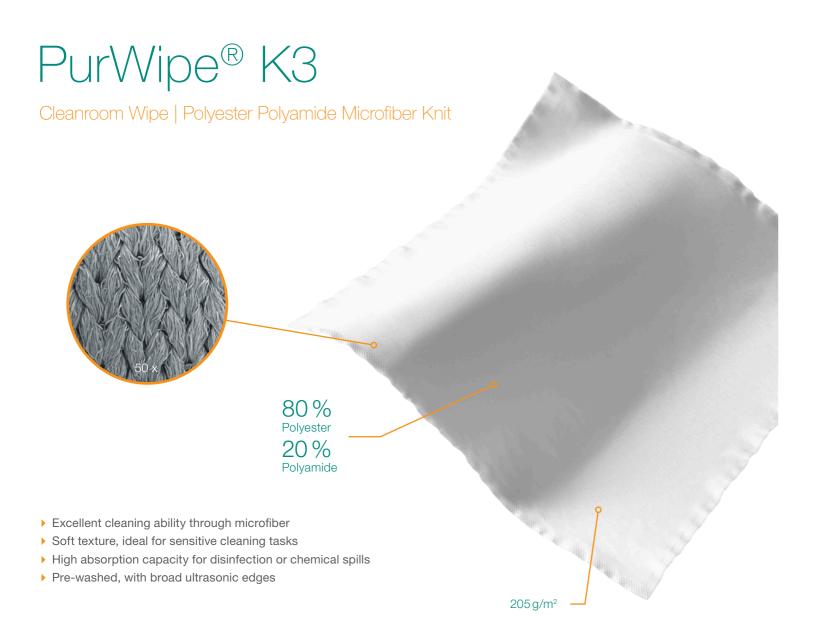
The PurWipe® K2 is a pure polyester microfiber wipe with a fine knit structure and soft texture, making it ideal for use on scratch-sensitive surfaces such as glass. The fine microfibers remove even the smallest particles without damaging the surface. If required, the K2 is also available as 4" or 6" wipe, making it ideal for cleaning of small mechanical or optical components.

#### Optionally available in different edges and sizes

K1-209	K1-212	K1-209-S [STERILE]	K1-212-S [STERILE
➤ Size: 23×23 cm   9×9"  ➤ Edges: Heat sealed	➤ Size: 30x30cm   12x12"  ➤ Edges: Heat sealed	➤ Size: 23x23cm   9x9"  ➤ Edges: Heat sealed	➤ Size: 30x30cm   12x12"  ➤ Edges: Heat sealed
Packaging: 150 pcs/bag (pack) 10 packs/case [1.500]	▶ Packaging: 150 pcs/bag (pack) 10 packs/case [1.500]	Packaging: 10 pcs/bag, 10 bags/pack, 10 packs/case [1.000]	Packaging: 10 pcs/bag, 10 bags/pack 10 packs/case [1.000]
▶ Item no.: 2183202	▶ Item no.: 2183204	▶ Item no.: 2183203	▶ Item no.: 2183205
(\2) ISO (3	3 4 5 6 7 8	( <u>2</u> ) ISO (	3 4 5 6 7 8
GMP	A/B C D	GMP	A/B C D

#### Optionally available in different sizes

K2-109	K2-112	K2-109-S [STERILE]	K2-112-S [STERILE]
▶ Size: 23x23cm   9x9"	▶ Size: 30 x 30 cm   12 x 12"	▶ Size: 23x23cm   9x9"	➤ Size: 30x30cm   12x12"
► Edges: Laser cut	► Edges: Laser cut	▶ Edges: Laser cut	► Edges: Laser cut
Packaging: 150 pcs/bag (pack) 16 packs/case [2.400]	<ul><li>Packaging:</li><li>100 pcs/bag (pack)</li><li>10 packs/case [1.000]</li></ul>	Packaging: 10 pcs/bag, 10 bags/pack, 10 packs/case [1.000]	Packaging: 10 pcs/bag, 10 bags/pack, 10 packs/case [1.000]
Item no.: 2183302	▶ Item no.: 2183304	▶ Item no.: 2183303	▶ Item no.: 2183305
1 ISO	3 4 5 6 7 8	1 ISO	3 4 5 6 7 8
GMF	A/B C D	GMP	A/B C D



PurWipe® K4 Cleanroom Wipe | 2-ply Polyester Knit 100% Polyester ▶ Double-layered embossed material ▶ Excellent fluid absorption ▶ Optimal for disinfecting stainless-steel surfaces ▶ Pre-washed, low particle emission  $270\,g/m^2$ 

2-ply material

The high-quality PurWipe® K3 cleanroom wipe has a thick knit material made with finest microfibers which make it perfectly suited for fine cleaning. It does not only offer a high absorbability for fluids, but also ensures that sensitive surfaces will not be scratched thanks to its soft texture.

The PurWipe® K4 is a special wipe made from an embossed, double-layered polyester knit. The high material weight allows this cleanroom wipe to absorb large amounts of fluid, making it ideal for absorbing spillages and for wiping large surfaces. The knitted material is extremely abrasion resistant and perfectly suited for safe cleaning and disinfection, even on rougher surfaces and stainless steel.

#### Optionally available in different edges and sizes

K3-309	K3-312	K3-309-S
▶ Size: 23x23cm   9x9"	▶ Size: 30x30cm   12x12"	▶ Size: 23x2
▶ Edges: Ultrasonic sealed	▶ Edges: Ultrasonic sealed	▶ Edges: Ultr
Packaging: 100 pcs/bag (pack) 20 packs/case [2.000]	Packaging: 100 pcs/bag (pack) 10 packs/case [1.000]	Packaging: 10 pcs/bag 10 packs/ca
▶ Item no.: 2183406	▶ Item no.: 2183408	▶ Item no.: 2
3 ISO GMP	3 4 5 6 7 8 A/B C D	

K3-309-S [STERILE]	K3-312-S [STERILE]	
▶ Size: 23×23cm   9×9"	▶ Size: 30x30cm   12x12"	
▶ Edges: Ultrasonic sealed	► Edges: Ultrasonic sealed	
Packaging: 10 pcs/bag, 10 bags/pack, 10 packs/case [1.000]	Packaging: 10 pcs/bag, 10 bags/pack, 10 packs/case [1.000]	
▶ Item no.: 2183407	▶ Item no.: 2183409	
1 item 110 2100407	Filem 110 2103409	
3 ISO GMP	3 4 5 6 7 8 A/B C D	

K4-309	K4-312	K4-309-S [STERILE]
➤ Size: 23x23cm   9x9"  ➤ Edges: Ultrasonic sealed	➤ Size: 30x30cm   12x12"  ➤ Edges: Ultrasonic sealed	➤ Size: 23x23cm   9x9"  ➤ Edges: Ultrasonic sealed
Packaging: 100 pcs/bag (pack) 8 packs/case [800]	Packaging: 100 pcs/bag (pack) 8 packs/case [800]	➤ Packaging: 5 pcs/bag, 10 bags/pack, 10 packs/case [500]
▶ Item no.: 2183600	▶ Item no.: 2183602	▶ Item no.: 2183601
3 ISO GMP	3 4 5 6 7 8 A/B C D	3 ISO GMP

K4-312	K4-309-S [STERILE]	K4-312-S [STERILE]
<ul> <li>Size: 30x30cm   12x12"</li> <li>Edges: Ultrasonic sealed</li> <li>Packaging: 100 pcs/bag (pack) 8 packs/case [800]</li> </ul>	<ul> <li>Size: 23x23cm   9x9"</li> <li>Edges: Ultrasonic sealed</li> <li>Packaging: 5 pcs/bag, 10 bags/pack, 10 packs/case [500]</li> </ul>	<ul> <li>Size: 30x30cm   12x12"</li> <li>Edges: Ultrasonic sealed</li> <li>Packaging: 5 pcs/bag, 10 bags/pack, 10 packs/case [500]</li> </ul>
▶ Item no.: 2183602	▶ Item no.: 2183601	▶ Item no.: 2183603
0 3 4 5 6 7 8 MP A/B C D	3 ISO 3	4 5 6 7 8 A/B C D

# Available edges PurWipe® V-Series

# Advantages of the V-Series

Ready-to-use, safe and convenient

#### Ready-to-use

The PurWipe® V-Series is not only immediately ready-to-use, it is also extremely comfortable. Each wipe can be removed individually and thanks to the correct dosage with 70/30 isopropanol, there is no need to use a separate disinfectant or a spray bottle.



#### Safe

PurWipe® V-Series wipes are filled and packed in a cleanroom to ensure a high cleanliness and compatibility with cleanroom application. All V-Series wipes are individually folded and stacked inside the pouch to allow single removal without the risk of contaminating the remaining wipes by the user. Each pouch is provided with a label showing the batch number, expiry date and a 'date opened' field for full quality control.



# Presaturated wipes

With our PurWipe® V-Series presaturated cleanroom wipes we have developed a wiping solution that is ready-to-use without the need of applying additional disinfectant. Safely packed in a resealable pouch, the premium quality wipes can be removed individually and used immediately. V-Series wipes eliminate aerosol-misting, the risk of incorrect fluid dosage and time-consuming handling.

Features of our presaturated cleanroom wipes

- ▶ Ready-to-use, presaturated with 70% IPA / 30% DI water
- Available in two different qualities (nonwoven and knitted)
- ▶ Processed and packaged in a cleanroom (ISO 5)
- ▶ Effective cleaning and disinfection performance

#### Convenient

The already presaturated wipes have the advantage that they eliminate spray mist and IPA aerosol in the environment by eliminating the need for additional spraying. As this wipe combines two products in one, it reduces the amount of consumables needing to be stored and transfered into the cleanroom and is therefore a much more comfortable solution for the user.



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# PurWipe® V3



The newly developed PurWipe® V3 wipe is characterized by its exceptionally robust material and great cleaning ability. The innovative microfiber nonwoven material consists of 100 % synthetic fibers without natural material such as cellulose and is therefore a cleaner alternative to traditional nonwoven wipes. V3 is ideally suited not only for general cleaning tasks in cleanrooms, but also for the disinfection of sensitive as well as rough surfaces, such as stainless steel. The wipes are ready-to-use presaturated in a resealable pouch and can be removed individually for safe handling. V3 is the innovative solution for GMP envirmonments where a high bioburden and fiber shedding of wipes needs to be avoided.

V3-109	V3-112	
▶ Size: 23x23cm   9x9"	▶ Size: 30x30cm   12x12"	
▶ Edges: Cut	▶ Edges: Cut	
➤ Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	
▶ Item no.: 2186100	▶ Item no.: 2186102	
1 ISO GMP	A/B C D	

V3-109-S [STERILE]	V3-112-S [STERILE]	
▶ Size: 23x23cm   9x9"	▶ Size: 30x30cm   12x12"	
▶ Edges: Cut	▶ Edges: Cut	
Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	
▶ Item no.: 2186101	▶ Item no.: 2186103	
1 ISO 3	3 4 5 6 7 8 A/B C D	

# PurWipe® V4



The high-quality PurWipe® V4 polyester wipe is a ready-to-use presaturated cleanroom wipe with a superior performance compared to common presaturated nonwoven wipes. It consists of a robust double knit material making it ideal for disinfection in GMP cleanrooms. Thanks to its three-dimensional structure it can effectively trap and remove particles from cleanroom surfaces and stainless steel. This premium wipe features heat sealed edges and is decontaminated multiple times and carefully inspected to ensure lowest particle emission and a high purity. These properties make the V4 suitable for even the most critical of cleanroom applications and for a wide range of uses.

V4-209	V4-212
▶ Size: 23x23cm   9x9"	▶ Size: 30x30cm   12x12"
▶ Edges: Heat sealed	► Edges: Heat sealed
▶ Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	➤ Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]
▶ Item no.: 2186000	▶ Item no.: 2186002

V4-209-S [STERILE]	V4-212-S [STERILE]	
▶ Size: 23x23cm   9x9"	▶ Size: 30x30cm   12x12"	
▶ Edges: Heat sealed	► Edges: Heat sealed	
▶ Packaging: 30 pcs/bag, 5 bags/pack, 4 packs/case [600]	<ul><li>Packaging:</li><li>30 pcs/bag, 5 bags/pack,</li><li>4 packs/case [600]</li></ul>	
▶ Item no.: 2186001	▶ Item no.: 2186003	
2 ISO 3 4 5 6 7 8 GMP A/B C D		

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Wipe Model: K1-Series

### Quality Control



PurWipe® cleanroom wipes are produced in a state-of-the-art production facility, certified according to ISO 9001, with ISO 4 to 7 category cleanrooms. Using specially designed production equipment and specialized methods, we provide premium-quality materials, which ensure high purity thanks to our ultraclean manufacturing process. Strict quality management and experienced production staff are part of our quality assurance as well as our certified in-house laboratory with extensive test equipment and test procedures according to valid standards and guidelines.

#### PurWipe® Highlights:

- ▶ Ultraclean manufacturing process from the first step our wipes are processed under cleanroom conditions
- ▶ State-of-the-art production facilities and machines for consistently high quality
- ▶ 100% inspection policy each wipe is checked
- ▶ Well thought out packaging concept for GMP-compliant entry into any cleanroom environment
- Batch-specific laboratory and product tests, and issuance of certificates of analysis
- ▶ Fully validated sterilization according to ISO 11137
- ▶ Sterility assurance level 10-6 with sterilization certificate

# In-house testing laboratory

Documentation

Extensive quality control checks as well as analytical tests are performed and documented for full quality assurance on all PurWipe® wipes. The following documents can be supplied with every delivery of PurWipe® products:

#### COA - Certificate of Analysis:

- NVR test: measurement of non-volatile residues
- LPC test: particle emission measurement for fluid-bound particles (liquid particle count)
- APC test: particle emission measurement for airborne particles (airborne particle count)
- ► Conformity declaration for release of each batch

#### For sterile goods:

COI (Certificate of irradiation) - Sterilization Certificate

# Custom solutions Our technical capabilities go far beyond the standard range of cleanroom wipes. If you have any special requirements – be it

Our technical capabilities go far beyond the standard range of cleanroom wipes. If you have any special requirements – be it regarding material composition, size, particle emission or packaging – please do not hesitate to contact us. We will be happy to develop the perfect cleanroom wipe for your application.



### Packaging Concept

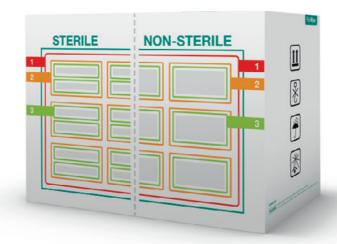
A detailed packaging concept along with cleanroom-suitable packaging materials are standard for all our PurWipe® wipes. The triple packaging allows contamination-free entry into any cleanroom area, while the batch-specific labelling on the inner packaging level provides maximum safety and traceability.

#### Highlights of the PurWipe® packaging:

- ▶ Bags are manufactured in a cleanroom
- Clear polybag with easy-tear function (allows safe and particle-free opening)
- ▶ Triple packaging as standard for sterile products
- Label with all relevant product details and batch information on each bag
- ▶ Colour-coding of labels for non-sterile and sterile products
- Gamma-irradiation indicator to check sterility of sterile products



Sterilization indicator



#### Outer packaging: [carton]

- Printed carton
- Label with all relevant details (batch number, expiry date, product details)

#### 1 Outer packaging: [carton liner]

▶ PE carton liner

#### 2 Secondary packaging: [pack]

- ▶ Sealed cleanroom HDPE bag
- ▶ With easy-tear function for easy opening

#### 3 Primary packaging: [bag]

- ▶ Sealed cleanroom HDPE bag
- ▶ With easy-tear function for easy opening
- Label with all relevant details (batch number, expiry date, product details)

#### Sterilization

The bioburden of cleanroom consumables is an important factor in all GMP-regulated cleanrooms. A wipe that is used for cleaning and disinfection of surfaces should not become a source of contamination itself. For GMP cleanroom classes C and above, we recommend the usage of sterile wipes – this is the only way to surely prevent that the wipe causes a microbial contamination of your cleanroom.

Sterile PurWipe® wipes are gamma sterilized and have a sterility assurance level (SAL) of 10<sup>-6</sup>. The sterilization process is fully validated according to DIN EN ISO 11137 and documented. The label includes a sterilization indicator, which allows you to check if the sterilization has been successful.







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