Low Endotoxin Products for Critical Environments

CONTEC®

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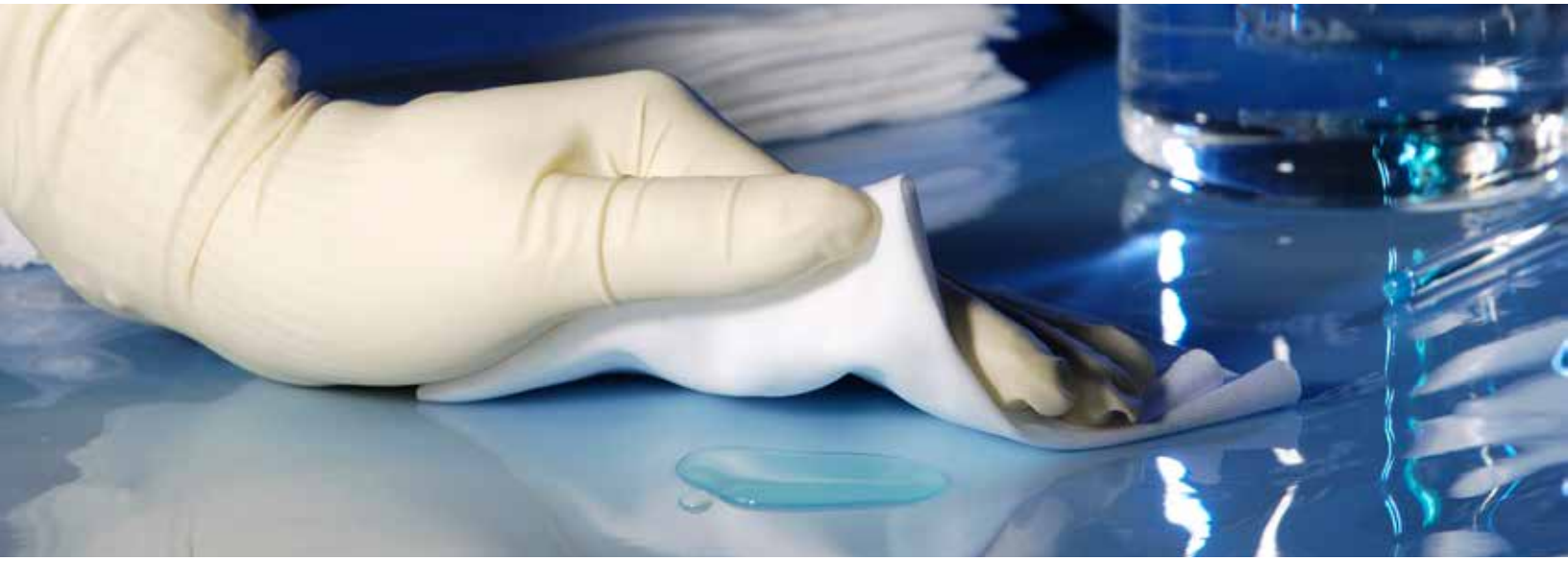

Contec, Inc. is a leading manufacturer of contamination control products for mission-critical cleaning in manufacturing environments worldwide. For more than 29 years, Contec has provided solutions to customers across many industries including biomedical, pharmaceutical, medical device, microelectronics, optics, semiconductor, data storage, automotive OEM and aerospace. Meeting customer needs in all these markets and exceeding customer expectations are part of our core values at Contec. This is a big difference between us and our competitors.

INNOVATION As a long established leader in custom designed products for specific applications, many Contec wipes and mops were developed through customer requests. We take pride in developing innovative products that not only deliver outstanding performance, but are cost-effective for our customers. We were the first to introduce presaturated wipes to critical environments, allowing customers to greatly reduce their VOC emissions. We were also the first to develop a lightweight wall mopping system for the biotech and life sciences market. We treat new applications and customer needs as a challenge to our R&D capabilities.

TECHNICAL SUPPORT Our success would not be possible without our technical support team. Contec has the largest, most experienced sales team in the critical environment industry and a technical support team with more than 100 years in critical environment solutions. Contec industry experts provide unmatched technical seminars and customer training. With sales representatives all over the world, our customers benefit from personalized service and fast, efficient sample and order turnaround.

GLOBAL SCOPE AND MULTIPLE MANUFACTURING FACILITIES We have state-of-the-art manufacturing in Spartanburg, South Carolina that serves as our Regulated Market Technology Center, and in Suzhou, China that serves as our Electronics Technology Center. In addition we have distribution centers in Toledo, OH and Vannes, France. We can provide the same products in all geographies, and our regional R&D centers allow us to develop products for specific applications in each region.

QUALITY Contec manufacturing facilities are ISO 9001:2008 registered. As a vertically integrated manufacturer, Contec controls more of the manufacturing process than any of our competitors. We invite you to come visit our manufacturing facilities and find out for yourself the quality built into the products we make.

BROAD CAPABILITY AND PRODUCT LINE Our extensive cleanroom product line includes knitted, woven and nonwoven wipes, presaturated wipes, sterile and non-sterile products, mopping systems, wall washing systems, disinfectants, sponges and swabs for cleanrooms and controlled environments. In fact, we have the widest variety of presaturated wipes and mopping systems in the industry. Still not convinced we're the cleanroom industry leader? Contact your sales representative and ask for a product sample. Our Samples Department takes care of both standard and custom product orders. Requests come in from all over the world and most are sent to customers within 48 hours. More than 6,700 samples were processed last year alone. So the obvious question isn't "Why Contec?" but instead, "Why not?"

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All sterile parts are validated sterile per the Association for the Advancement of Medical Instrumentation (AAMI) 11137 Guidelines to a 10^{-6} Sterility Assurance Level.

STERILE LE LOW ENDOTOXIN

VALIDATED 10^{-6} STERILE

CONTEC®

Endotoxin Control

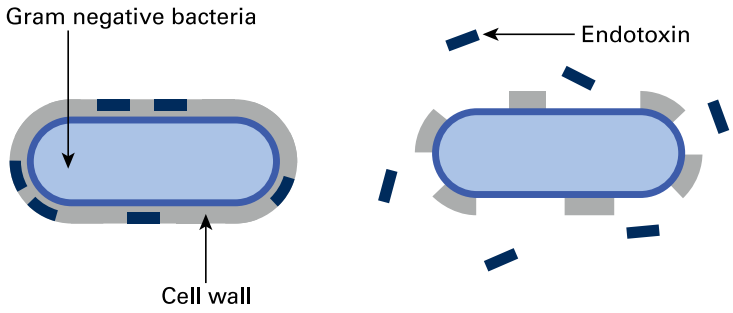
"Unlike viable microbial contamination, pyrogens are difficult to remove and deactivate."

The presence of pyrogens is a critical safety concern with injectable products and medical devices as products contaminated with pyrogens can pose a life-threatening risk to patients. Unlike viable microbial contaminants which can be destroyed by various sterilization techniques, pyrogens are difficult to remove and deactivate.

Pyrogens are fever-producing substances (from pyro the Greek word for fire) released from the outer membranes of decaying bacteria. Bacterial endotoxin, specifically from the outer membranes of gram negative bacteria, are the most common pharmaceutical pyrogens, so much so that the term is often used interchangeably. Bacterial endotoxins are members of a class of phosolipids called lipopolysaccharides (LPS). The release of LPS from bacteria takes place after the cell death and bursting of the cell wall. Examples of endotoxin-releasing, gram-negative bacteria are *E. coli*, *Pseudomonas aeruginosa*, *Enterobacter aerogenes,* and *Klebsiella pneumoniae*.

Endotoxin Limits

The FDA sets the limits for pharmaceutical products produced in the US or imported into the US. Endotoxin is expressed in International Units (IU) of endotoxin although Endotoxin Unit (EU) is still commonly used. One International Unit of endotoxin is equal to one Endotoxin Unit. The limits for endotoxins are stated in the USP chapter< 161>, Transfusion and Infusion Assemblies and Similar Medical Devices. The USP requirement for medical devices specifies a limit of 0.5 EU/mL or 20 EU/device for products that directly or indirectly contact the cardiovascular and lymphatic systems. The limit for products in contact with the Cerebrospinal fluid is 0.06 EU/mL or 2.14 EU/device.



Sources of Endotoxin

There can be several sources of endotoxin in parenteral and medical device products. Usual sources are the water used either as the solvent or in the processing, packaging components, chemicals and raw materials or equipment used in the preparation of the product. Control of the microbiological and endotoxin levels in these areas can help keep endotoxin limits under their required limits for the finished product, i.e. the use of endotoxin-free glassware and implements, the use of water for injection or process water that has been treated to have less than 0.25 EU/ml and to use raw materials and chemicals from a reputable source with confirmed endotoxin limits.

"The use of low endotoxin products for cleaning and contamination control can help to minimize the risk of endotoxin contamination."

Preventing Endotoxin Contamination

Endotoxins are very difficult to remove as they vary in molecular weight and are tolerant to changes in pH and temperature. Obviously sterilization is not the answer; the endotoxins are already dead (as previously mentioned) and released from the decaying outer cell walls of gram-negative bacteria. The FDA Inspection Technical Guide states that:

"It is difficult to remove endotoxins from products once present. It is far better to keep finished products and components relatively endotoxin free rather than have to remove it once present."

Water for Injection (WFI) is used in the production of parenteral drugs and other critical products when endotoxin levels must be controlled. The limits for bacterial endotoxins in WFI are ≤ 0.25 EU/mL or ≤0.25 I.U./mL as stated in the USP Monograph on Water for Injection and the European Pharmacopoeia, Water for Injection Monograph, respectively.

There are no regulations for endotoxin levels in cleanroom wipes and alcohol products, however, convention is that low endotoxin products meet the USP requirement of <0.5 EU/mL or <20 EU/device. Products certified as low endotoxin are not required to use low endotoxin ingredients, but the final product must be tested for conformance to USP requirements for endotoxin levels. Finished products containing WFI have a component (water) that is low endotoxin, but for the finished product to be classified as low endotoxin, it must be tested to meet the stated limits to ensure all components of the product, packaging and manufacturing cycle have been controlled to produce a low endotoxin result.

Control of process water, raw materials and production equipment all contribute to prevent endotoxin contamination of the finished product throughout the process. The use of a complete range of low endotoxin contamination control products will prevent addition of further bioburden or endotoxins into the manufacturing process and product contact areas.

Contamination Control Consumables

The use of low endotoxin products for cleaning and contamination control can help to minimize the risk of endotoxin contamination of a pharmaceutical product.

Contec can offer a full line of low endotoxin certified products, including presaturated wipes, dry knit and nonwoven wipes, and sterile 70% isopropyl alcohol, for the most critical applications. Each lot is tested before release to ensure a guaranteed low level of endotoxin.

Sterile 70% IPA and a 6% hydrogen peroxide solution are both available with a guaranteed endotoxin limit of 0.25 EU/ml. To compliment these, a range of dry wipes are also available with guaranteed low endotoxin levels. The cost effective Amplitude Kappa LE is a polyester/lyocell hydroentangled wipe, double bagged in small quantities with an endotoxin limit of 20 EU per wipe. Sterile Polynit Heatseal Low Endotoxin Wipes, made from 100% knitted polyester with sealed edges have an endotoxin limit of 1 EU per wipe. These wipes are triple bagged and also have very low levels of particles and fibers.

For greater convenience, presaturated wipes with 70% IPA could be used. Knitted polyester or meltblown polypropylene pouch wipes are available, depending on the levels of particles and fibers that are also required.

All of Contec's low endotoxin contamination control consumables are lot tested using the Limulus Amebocyte Lysate test for quantification of endotoxin levels.

The blood of the prehistoric horseshoe crab is used to carry out the Limulus Amebocyte Lysate (LAL) test for detection and quantification of bacterial endotoxin.

Presaturated wipe with IPA and WFI has a guaranteed endotoxin level of <1EU/wipe.

PROSAT® *Sterile*™ Knitted Wipes

Presaturated knit wipes with a blend of 70% IPA and 30% Water for Injection (WFI)

PROSAT® *Sterile* Low Endotoxin Wipes are made of 100% knitted polyester Polynit Heatseal, presaturated with a blend of 70% IPA and 30% Water for Injection (WFI). Each lot is tested before release and low endotoxin certified to less than <1EU/wipe.

The sealed edge wipe produces very low levels of particles and fibers and is ideal for use on product contact surfaces. Each resealable pouch contains a small number of wipes, eliminating any waste at the end of a session. Each pouch is individually bagged for easy entry into the sterile suite.

Presaturated wipes provide many benefits including solvent control, reduced Volatile Organic Compounds (VOC's) and increased process control and repeatability. The resealable pouch reduces waste. PROSAT *Sterile* Low Endotoxin Wipes are validated sterile and suitable for use in aseptic suites and the most critical pharmaceutical cleanrooms.

Part No.	Description	Quantity
PSWE0001	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA/30% WFI, 9" x 9" (23 x 23cm), half-folded, triple bagged, sterile	10 wipes/pouch; 55 pouches/case
PSWE0002	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA/30% WFI, 12" x 12" (30 x 30cm), flat stacked, double bagged, sterile	30 wipes/pouch; 15 pouches/case
PSWE0003	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA/30% WFI, 12" x 12" (30 x 30cm), half-folded, triple bagged, sterile	10 wipes/pouch; 30 pouches/case

"Each lot is tested and low endotoxin certified to <20EU/wipe."

PROSAT® *Sterile*™ Nonwoven Wipes

Presaturated nonwoven wipes with a blend of 70% IPA and 30% deionized water

Contec's PROSAT® *Sterile* Polypropylene Low Endotoxin wipes are presaturated with 70% USP Grade IPA and 30% Deionized Water. The meltblown polypropylene wipes provide a consistent release of solvent to thoroughly remove surface contaminants in critical environments.

Each lot is tested before release and low endotoxin certified to <20 EU/wipe, eliminating the risk of introducing endotoxins and other contaminants into product contact areas.

The resealable pouch reduces waste and the presaturated wipe controls solvent usage and VOC's. PROSAT *Sterile* Polypropylene Low Endotoxin Wipes are validated sterile and compatible with ISO Class 5 (Grades A/B) environments.

Part No.	Description	Quantity
PS-911LE	PROSAT *Sterile* Polypropylene LE Wipes, 9 x 11" (23 x 28cm), double bagged, sterile	30 wipes/pouch; 36 pouches/case

100% knitted polyester with sealed edges and certified endotoxin level of <1 EU/wipe.

Sterile Dry Knitted Wipes

Knit polyester low endotoxin wipes with sealed edges

Polynit Heatseal Low Endotoxin Wipes are manufactured from high quality 100% knitted polyester fabric with sealed edges and produce low levels of particles and fibers. The polyester fabric offers the widest range of solvent compatibility. Each lot is tested before release and low endotoxin certified to <1 EU/wipe.

The wipes are half-folded and triple packaged in linear tear outer bags for ease of transfer into ISO Class 5 (Grades A/B) cleanrooms. This smaller packaging takes up less space making it ideal for use in isolators and RABS. The small quantity of wipes per package can be used during one cleaning session, eliminating waste.

Polynit Heatseal Low Endotoxin Wipes are validated sterile and ideal for use in product contact areas.

Part No.	Description	Quantity
LWLE0001	Polynit Heatseal LE Wipes, 9" x 9" (23 x 23cm), half-folded, triple bagged, sterile	10 wipes/bag; 50 bags/case
LWLE0002	Polynit Heatseal LE Wipes, 12 x 12" (30 x 30cm), half-folded, triple bagged, sterile	10 wipes/bag; 36 bags/case

"Packaged in smaller quantities - ideal for use in aseptic processing areas."

Sterile Dry Nonwoven Wipes

Dry nonwoven low endotoxin wipes with good sorbency

Amplitude™ Kappa™ Sterile LE Wipes are made with Sontara® lyocell/polyester blend fabric. These low endotoxin wipes have excellent sorbency and are validated sterile. Amplitude Kappa Sterile LE wipes are lot tested and low endotoxin certified to <20 EU/wipe.

The packaging allows for easy opening even when wearing gloves and the small quantities per pack minimize the possibility of any wastage. These wipes are ideal for use in aseptic processing areas, areas when increased sorbency is needed or a textured surface is required for efficient cleaning and particle removal. The wipes are also highly suitable for spill control and wiping-to-dry.

Part No.	Description	Quantity
NWPZ0001	Amplitude Kappa Sterile LE Wipes, 9 x 9" (23 x 23cm), sterile	25 wipes/bag; 10 bags/case
NWPZ0002	Amplitude Kappa Sterile LE Wipes, 12 x 12" (30 x 30cm), sterile	25 wipes/bag; 10 bags/case

Filtered to 0.2µm
to assure sterility.

Irradiated 70% IPA Solution

Certified low endotoxin 70% USP Grade Isopropanol

Contec Low Endotoxin Irradiated Alcohol contains 70% by volume USP Grade Isopropanol (IPA) and 30% Water for Injection (WFI). The alcohol blend is 0.2 micron filtered, filled under Grade A unidirectional airflow and bagged in a Grade C/ISO Class 7 cleanroom. This clean manufacture coupled with water for injection means the alcohol blend is guaranteed and certified to have an endotoxin level < 0.25 EU/ml, making it suitable for product contact surfaces. The bottles are provided with the triggers installed preventing any possible chance of contaminating the irradiated solution installing a trigger. The bottles are double bagged in linear tear bags, and irradiated at no less than 25kGy. Each lot is sterility tested and certified.

Available as a 17 oz and 32 oz trigger spray bottle, the trigger sprays are fitted with a protected system, which ensure sterility throughout use. Each bottle has a lot code and expiration date for easy record keeping.

Part No.	Description	Quantity
SBT167030LE	Contec Sterile 70% IPA/30% WFI LE, 17 oz. (0.5L), trigger spray, sterile	8 bottles/case
SBT347030LE	Contec Sterile 70% IPA LE/30% WFI LE, 34 oz. (1L), trigger spray, sterile	6 bottles/case

"Blend of hydrogen peroxide and WFI with a guaranteed endotoxin level of 0.25 EU/ml."

Hydrogen Peroxide Solution

Sterile fill low endotoxin cleaner with hydrogen peroxide

Contec HydroKlean is a blend of 6% hydrogen peroxide and water for injection in a 17 oz (0.5L) and 34 oz (1L) bottle with installed trigger sprayer as well as a 170 oz (5L) capped container. It is ready to use and has no Volatile Organic Compounds (VOC's). It leaves little to no residue, is sterility tested and has a certified endotoxin level of <0.25 EU/ml making it ideal for use in product contact areas.

Hydrogen peroxide is not classed as corrosive and can be used safely in all areas of a cleanroom.

The product is 0.2µm filtered and sterile filled into pre-irradiated containers under Grade A unidirectional airflow and bagged in a Grade B/ ISO Class 5 cleanroom. The 17 oz (0.5L) and 34 oz (1L) "bag in bottle" system protects contents during use. A certificate of analysis and sterility is provided for every batch.

HydroKlean is double or triple bagged allowing for ease of entry into controlled environments. It is easy to open even when wearing gloves.

Part No.	Description	Quantity
SBT17HKLE	Contec HydroKlean, sterile fill, 17 oz (0.5L), trigger spray, triple bagged	8 bottles/case
SBT34HK6IR	Contec HydroKlean, sterile fill, 34 oz (1L), trigger spray, triple bagged	6 bottles/case
SBC170HKLE	Contec HydroKlean, sterile fill, 1.3 US Gal. (5L), capped container, double bagged	2 containers/case

Contec® cleaning and disinfecting products are available throughout the world. Sales representatives are conveniently located across Europe, Asia, and North and South America. Please visit **www.contecinc.com** to find a sales representative in your area and to learn more about our products for critical environments.

Presaturated Wipes
Mopping Systems
Disinfectants
Spill Control Products
Knitted Wipes
Sterile Products
Sponges
Nonwoven Wipes
Swabs

NORTH AMERICA
Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA

Tel: +1 (864) 503-8333
Fax: +1 (864) 503-8444
Toll Free US, Canada, PR: 1-800-289-5762

EUROPE
Contec
ZI du Prat - RP 3707
56037 VANNES Cedex
FRANCE

Tel: +33(0) 2 97 43 76 98

ASIA
Contec Cleanroom Technology (Suzhou) Co. Ltd.
17 Longyun Road
Suzhou Industrial park
Suzhou 215026
China

Tel: +86-512-6274 4050
Fax: +86-512-6274 4051

www.contecinc.com

Contec is an ISO registered company. Please visit our web site to view our most current certification.

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