

Indigo-Clean[®]

Healthcare Luminaires
Continuous Dual-Mode Visible Light Disinfection



A brand of **legrand[®]**

KEVAL[®]

Indigo-Clean: Revolutionizing Health Care Disinfection With Visible Light

Since its introduction in 2015, Indigo-Clean Visible Light Disinfection has been partnering with health care facilities across the United States to kill dangerous bacteria and reduce Healthcare Acquired Infections (HAIs). In fact, a peer-reviewed study published in the American Journal of Infection Control documents a 73% reduction in surgical site infections at Maury Regional Medical Center in Columbia, Tennessee. And other facilities have reported similar results – sometimes even better.

Indigo-Clean's simple-to-use, dual-mode technology provides ambient light with disinfection in occupied spaces, and switches automatically to Indigo mode to maximize disinfection in unoccupied spaces. Unlike UV, it is safe. Unlike other visible light disinfection products, it's proven. Our data tells a story and the story is about how we can help you make HAIs history. **Join us.**

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Why Indigo-Clean?

The problem:

Current environmental disinfection methods are short-lived, and harmful bacteria begin repopulating the space as soon as cleaning is complete.

The solution:

Indigo-Clean is a patented, dual-mode environmental disinfection technology that uses visible light to safely, automatically and continuously kill harmful bacteria, 24/7, in the air, and on hard and soft surfaces. It also prevents bacteria from repopulating the space, consequently bolstering current infection prevention efforts.

What makes Indigo-Clean Unique:

- Indigo-Clean is an environmental disinfection device that is integrated into your lighting
- Indigo-Clean kills bacteria in the air, and on hard and soft surfaces, which are often missed during routine cleaning
- Indigo-Clean requires no special training, additional staff, or consumables to operate
- Indigo-Clean is **NOT UV** light... it uses *safe* 405nm visible light

Recommended Use Areas

Operating Rooms



The main concern is Staph Aureus, which results in real-time contamination.

Emergency Departments



Harmful bacteria is transmitted from the ED to other areas of the hospital.

Patient Bathrooms



Hotspot for *C. diff*, which are notoriously difficult bacteria to kill.

Procedure/Exam Rooms



The main concern is Staph Aureus, which results in real-time contamination.

Hospital Pharmacies



Helps healthcare pharmacies meet USP 797/800 standards for the safe handling of hazardous drugs.



How Does Indigo-Clean Work?

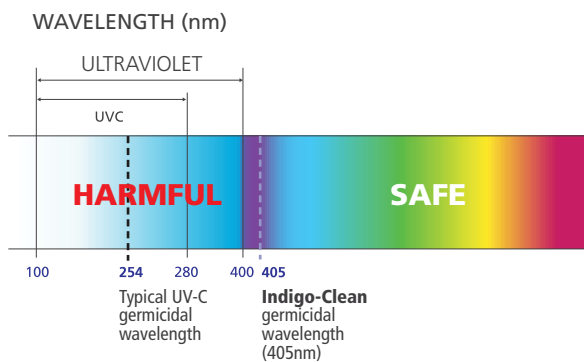


Indigo-Clean requires no line of sight to disinfect, but instead reflects off surfaces, disinfecting everywhere the light reaches.

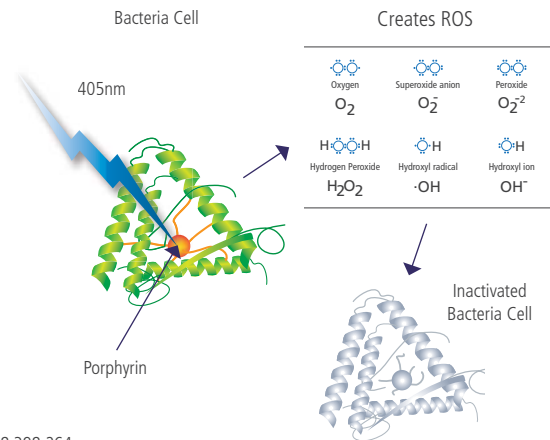
How It Works*:

- The 405nm emitted from Indigo-Clean luminaires reflects off of walls and surfaces, penetrating harmful micro-organisms
- The 405nm light targets and excites naturally occurring molecules within the bacteria called porphyrins, to produce intra-cellular Reactive Oxygen Species (ROS).
- Similar to bleach, these ROS create an oxidative environment within the organism, inactivating it and preventing it from re-populating the space.

Visible light spectrum showing the active element in Indigo-Clean



Inactivation of bacteria via visible light absorption



* Indigo-Clean products and technology covered by U.S. Patent No. US 9,039,966 and US 8,398,264. May also be covered by patents found at www.kenall.com/patents. Other patents pending.

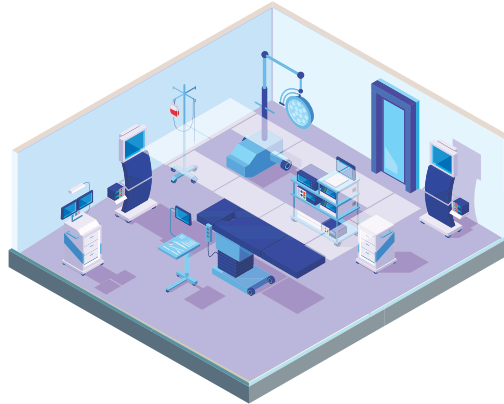
Automatic Controls and Two Operating Modes Make Indigo-Clean Effortless

Dual Mode Operation for Optimal Disinfection



White Disinfection Mode

Provides comfort and visual acuity, during procedures and cleaning; combines ambient white and indigo light for continuous visible light disinfection.



Indigo Disinfection Mode

Typically used when the room is not in use. Indigo disinfection mode provides optimal continuous visible light disinfection.

IC100: Automatic Proprietary Controls



During periods of occupancy, this IC100 control system is designed to set the Indigo-Clean fixtures into **White Disinfection Mode**, which provides comfortable white light, yet maintains a level of continuous disinfection to harmful bacteria. After the room has been unoccupied for 15 minutes (factory preset, field adjustable from 3 seconds to 30 minutes), the control system will set the Indigo-Clean luminaires to **Indigo Disinfection Mode**, which provides maximum disinfection of harmful bacteria.

What Does Indigo-Clean Kill?

ESKAPE Pathogens:

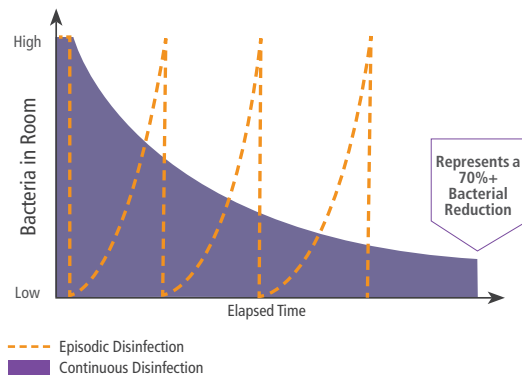
- E**nterococcus faecalis
- S**taphylococcal Aureus (incl. MRSA)¹
- K**lebsiella pneumoniae
- A**cinetobacter baumannii
- P**seudomonas aeruginosa
- E**nterobacter species

As well as a range of other organisms:

- *C. diff*¹
- VRE
- *Aspergillus niger*
- *E.coli*
- *Salmonella enteritidis*

Continuously Reduce Harmful Bacteria by 70%+ with Indigo-Clean

Continuous vs. Episodic Disinfection



Clinical testing shows Indigo-Clean achieves a continuous 70%+ reduction of harmful bacteria² in the environment. At the same time, a recently published peer-reviewed, clinical study shows a 73% reduction in surgical site infections (SSIs).³

These results, combined with the average annual cost per patient due to HAIs, means that preventing even a single infection creates a positive ROI and drives down costs for healthcare providers.

1: *Antimicrobial Activity of a Continuous Visible Light Disinfection System* by Rutala, et. al, ID Week 2016

2: Maclean M., S.J. MacGregor, J.G. Anderson, G.A. Woolsey, J.E. Coia, K. Hamilton, I. Taggart, S.B. Watson, B. Thakker & G. Gettinby (2010). *Environmental Decontamination of a Hospital Isolation Room using High-Intensity Narrow-Spectrum Light*. *Journal of Hospital Infection*, 76(3); 247-251. DOI: 10.1016/j.jhin.2010.07.010

3: *Am J Infect Control*. 2019 July;47(7):804-810

Clinical Effectiveness

AJIC Peer Reviewed Study Results Show a 73% Reduction in SSIs

Goal

To reduce the number of surgical site infections (SSIs) with the addition of the Indigo-Clean Visible Light Disinfection (VLD) system.

Methods

Indigo-Clean was installed into one orthopedic OR and its effect on bacteria levels throughout the room was measured using Baird Parker Agar (BPA) contact media for a period of 30 days. During this time, each room was cleaned using the facility's standard work process. Infection rates were compared one year before and after the VLD system implementation.

Results

The results from the test room show a continuous, average bacterial reduction of up to 88% from the sampled surfaces as compared to those in the two weeks before and after the VLD system installation.

Surgical site infections were tracked for 12 months and showed a 73% reduction in the test room as compared to the baseline period.

Maury Regional Medical Center, Columbia, TN

Room	Oct-2015 to Oct-2016		Oct-2016 to Oct-2017		SSI Change	Bacterial Reduction
	# of Cases	# of SSI	# of Cases	# of SSI		
OR-2 (with IC)	778	11	850	3	>=-73%	>=-85%
OR-3 (Distant Control)	751	6	809	7	<=+17%	Not Measured



Read the full AJIC peer-reviewed article at www.indigo-clean.com



Sealed Indigo-Clean Visible Light Disinfection Fixtures Help Hospital Pharmacies Meet USP 797/800 Standards



USP 797 describes the proper guidelines as established by the U.S. Pharmacopeial Convention, for sterile compounding of both hazardous and nonhazardous drugs; preventing harm to patients resulting from contamination of sterile products. However, USP 797 does not address the safe handling of hazardous drugs to protect staff and the environment, as well as patients.

Published on February 1, 2016 with a target implementation date of December 2019, **USP 800** outlines new standards for handling hazardous drugs that promote the safety of patients, personnel and the environment. It describes the entire drug handling process, from receipt to the proper disposal of both sterile and nonsterile products.

CSEDOIC Combines the Sealed Performance of Cleanroom Luminaires with the Disinfection Power of Indigo-Clean



The new CSEDOIC Series fixtures are certified to meet USP 797 and 800 requirements that protect compounding personnel from accidental exposure to hazardous drugs. The fixtures are built to strict standards for ingress protection and biohazard safety level 3-4. At the same time, Indigo-Clean visible light disinfection kills any harmful bacteria that may have been inadvertently introduced into the cleanroom environment, preventing accidental contamination of sterile preparations, thereby protecting patients.

See page 15 for CSEDOIC specifications.

Continuous Visible Light Disinfection via Automated, Dual-Mode Operation



Project: Maury Regional Health Center
Location: Columbia, TN



"We believed that Indigo-Clean would give us a substantial improvement in our disinfection given the prior research with environmental reduction in bacteria, but we were thrilled when we experienced a 73% reduction in SSIs."

– Lynnelle Murrell, Director of Infection Prevention
Maury Regional Medical Center, Columbia, TN



Indigo-Clean®

Reducing Harmful Bacteria *and* Surgical Site Infections

Indigo-Clean surgical suite fixtures are dual-mode luminaires that use an occupancy sensor to provide an effortless transition between white disinfection mode when the room is in use, and indigo disinfection mode when the room is not. Both modes provide the continuous visible light disinfection required to reduce harmful bacteria and surgical site infections in busy surgical suites.



M4SEDIC Series

- Delivered lumen range: 5,576 – 14,712 lm
- Input power: 68 – 149W
- Two operational modes: White and Indigo Disinfection Modes
- High performance LED arrays provide uniform lens appearance
- Diffused high-efficiency lens for reduced glare
- Antimicrobial finish

Nominal Sizes: 1' x 4'; 2' x 2'; 2' x 4'
 Installation Types: Grid, flange
 Lamp Types: White LED, 405nm Indigo LED

M4DLIC6 Series

- Delivered lumen range: 1,214 – 2,330 lm
- Input power: 33W, 39W
- Two operational modes: White and Indigo Disinfection Modes
- High performance LED arrays provide uniform lens appearance
- Antimicrobial finish

Nominal Sizes: 6" Aperture
 Installation Types: Recessed
 Lamp Types: White LED, 405nm Indigo LED



Kill Harmful Bacteria, Including *C. diff* and MRSA to Keep it from Spreading

In specified treatment areas, Indigo-Clean luminaires support the patient, the patient care team and the hospital environment by killing harmful bacteria, including MRSA** and *C. diff*, as well as other **ESKAPE** pathogens, when the room is in use. They are also sealed to help prevent the spread of infection, making them ideal for use in emergency departments, waiting rooms, procedure rooms and restrooms.



MEIC Series

- Delivered lumen range: 3,168 – 8,593 lm
- Input power: 33 – 75W
- Two operational modes: White and Indigo Disinfection Modes
- High performance LED arrays provide uniform lens appearance
- Antimicrobial finish

Nominal Sizes: | 2' x 2'; 2' x 4'
 Installation Types: | Grid, Flange
 Lamp Types: | White LED, 405nm Indigo LED



*per independent lab report #SGS-09S17036476; Contact Kenall Lighting for a copy of this report.

**Antimicrobial Activity of a Continuous Visible Light Disinfection System by Rutala, et. al, ID Week 2016



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This product complies with the Buy American Act: manufactured in the United States with more than 50% of the component cost of US origin. It may be covered by patents found at www.kenall.com/patents. Content of specification sheets is subject to change; please consult www.kenall.com for current product details.

Indigo-Clean®

Kill *C.diff* in Patient Bathrooms

Indigo-Clean downlights are ideal for use in patient restrooms where *C. diff* is often a critical concern.



MDLIC6 Series

- Delivered lumen range: 1,384 – 2,050 lm
- Input power: 29, 40W
- Two operational modes: White and Indigo Disinfection Modes
- High performance LEDs deliver high visual acuity
- Provided IC75 occupancy sensor system; switches automatically to maximum disinfection mode when room is unoccupied

Nominal Sizes:	6" Aperture
Installation Types:	Recessed
Lamp Types:	White LED, 405nm Indigo LED

**Sporicidal Disinfection
Kills 70% of *C. diff*
in 24 hours**

SGS Lab Report# - 09S17053798



Meeting Stringent USP 797/800 Requirements

Hospital compounding pharmacies handle dangerous and/or hazardous drugs that can cause problems for the people dispensing, delivering and receiving treatment. Such health problems can be reduced by following USP 797/800 requirements. Kenall's CSEDOIC series is an excellent example of a light fixture that provides the highest level of certification and reliable seal that compounding pharmacies require.



NEW CSEDOIC Series

- Delivered lumens range: 5,576 – 14,712 lm
- Input power: 68 – 149W
- Two operational modes: White and Indigo Disinfection Modes
- High performance LED arrays provide uniform lens appearance
- Diffused high-efficiency lens for reduced glare
- Smooth overlapping doorframe and lens for infection control and simplified cleaning protocols
- Provided IC150 occupancy sensor system; switches automatically to maximum disinfection mode when room is unoccupied

Nominal sizes: | 1' x 4'; 2' x 2'; 2' x 4'
 Installation Type: | Universal installation into 1.0" and 1.5" grid or flange (drywall) ceilings
 Lamp Types: | White LED, 405nm Indigo LED



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Who's Using Indigo-Clean?



"We wanted a disinfectant technology that would be effective, efficient and easy to use, which is exactly what Indigo-Clean is. Compared to other disinfecting technologies on the market, Indigo-Clean was the most cost-effective and efficient since there was no room downtime. And because it's automatic, it alleviates the concern of training and human error."

– **Mike Pankey, Administrator,**
Ambulatory Surgery Center
(ASC) of Spartanburg



"We chose to invest in Indigo-Clean for our operating room lighting not only because of the proven high antimicrobial rates, but we appreciated the ease of use, and the ability to continuously disinfect our operating rooms without any downtime. That translates into more procedures and more revenue for us."

– **Thomas Ragukonis, MD,**
Medical Director, New Century
Spine & Outpatient Surgical Institute



"We chose to partner with Indigo-Clean over other disinfecting technologies because of the ease of use and the proven efficacy of the disinfecting lights. We look forward to expanding our usage of Indigo-Clean in other areas of the hospital in the future."

– **Lisa Sherman, Director,**
Operating Room,
Holy Family Memorial



"Maintaining a safe, clean environment for our patients is our number one priority. Indigo-Clean safely, automatically, and continuously disinfects the environment, which means there is no need for room downtime when it (the operating room) is in use."

– **Sam Kaufman, CEO & Managing**
Director, Henderson Hospital



"Providing high-quality patient care, while maintaining a safe, clean environment for our patients is our number one priority. Knowing Indigo-Clean is a proven disinfectant technology, we felt it was important to partner Indigo-Clean with our current cleaning protocols within our new hybrid cardiac suite."

– **Leonard Freehof, CEO/Managing**
Director, Spring Valley Hospital

"...Indigo-Clean was the most cost-effective and efficient" - M. Pankey

..."continuously disinfect our operating rooms without any downtime. That translates into more procedures and more revenue for us." - T. Ragukonis

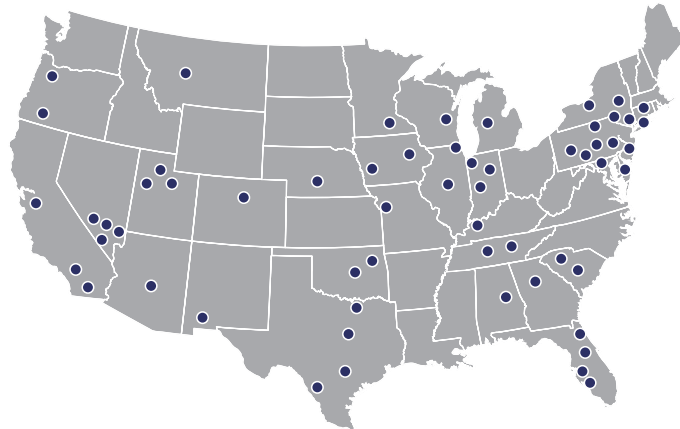
..."ease of use and the proven efficacy" - L. Sherman

..."Indigo-Clean is a proven disinfectant technology" - S. Kaufman

Nationwide, healthcare facilities are experiencing positive results with Indigo-Clean visible light disinfection.

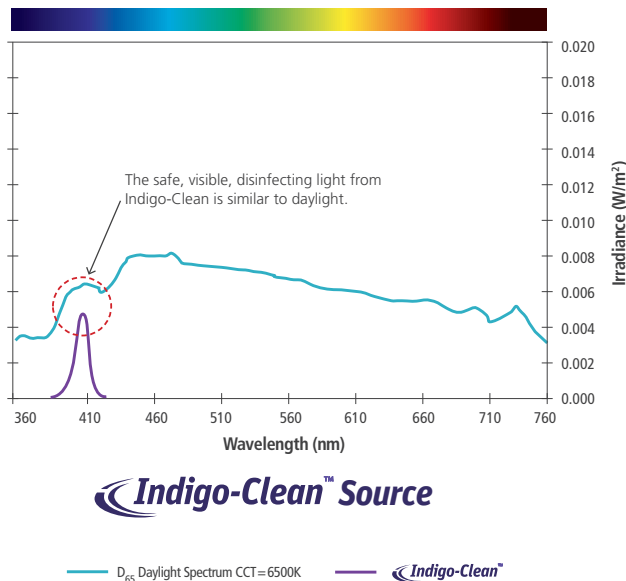
Select installations include:

- Maury Regional Medical Center, Columbia, TN
 - Universal Health Services, (Various Locations)
 - UMC – Las Vegas, NV
 - Nicklaus Children’s, Miami, FL
 - Tampa General, Tampa, FL
 - University of Utah, Salt Lake City, UT
 - Texas Health Resources, Ft. Worth, TX
 - Northwell Health, Brooklyn, NY
 - Advocate Condell – Northbrook, IL
 - Penn Medicine, New Brunswick, NJ
 - Mosaic Life Center – Kansas City, MO
 - Naviscent, Macon GA
 - Northside Hospital – Atlanta, GA
 - St. Luke’s, Bethlehem, PA
 - Allegheny Health Network – Pittsburgh, PA
 - Geisinger Medical Center, Danville, PA
- ... and many more



Safety Information

Comparison of Indigo-Clean with Daylight



Safety Testing

Indigo-Clean has been evaluated against existing visible light safety standards.

Standard	Testing Method	Results
IEC 62471/62778 ^{1,2}	Independent 3rd Party Laboratory	Pass (Exempt)
ACGIH ³	Self-Assessment	Pass
ICNIRP ^{4,5}	Self-Assessment	Pass

1: International Electrotechnical Commission – Photobiological safety of lamps and lamp systems, 2006
 2: International Electrotechnical Commission – Application of IEC 62471 for the assessment of blue light hazard to light sources and luminaires, 2014
 3: American Conference of Governmental Industrial Hygienists – Threshold Limit Values (TLVs) & Biological Exposure Indices Signature Publications, Cincinnati, 2007
 4: International Commission on Non-Ionizing Radiation Protection – Guidelines on limits of exposure to optical radiation from 0.38 to 3.9 mm. Health Physics 73; 539-555; 1997
 5: International Commission on Non-Ionizing Radiation Protection – Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent radiation) Health Physics 87, 171-186; 2004



Listings, Certifications

Fixtures designed for use in healthcare settings must satisfy a large number of demanding lighting and environmental requirements. Listings applicable to these requirements are shown below. Please refer to the www.indigo-clean.com to determine product specific listings.



ADA Compliant — Although ADA is not specific to lighting, it does impact fixture design by creating standards for wall sconce projection space and hanging light clearance. Section 4.4 of the ADA states that "objects projecting from walls with their leading edges between 27" and 80" above the finished floor shall protrude no more than 4" into walks, halls, corridors, passageways or aisles."



CCEA Approved — The City of Chicago Environmental Air (CCEA) rating ensures that the luminaire is inherently airtight. Wiring and/or branch circuit terminations are sealed off and gasketed from the plenum air space. This listing ensures that the luminaire is sealed to limit air flow from the room side to the plenum.



ETL — A product bearing the ETL Listed Mark is determined to have met the minimum requirements of prescribed product safety standards as certified by a Nationally Recognized Testing Laboratory (NRTL). The mark also indicates that the manufacturer's production site conforms to a range of compliance measures and is subject to periodic follow-up inspections to verify continued conformance.



IP64 — UL Certified IP64 per IEC 60598 ensures that the enclosure is dust-tight and protected against splashing water without any harmful effects.



IP65 — UL Certified IP65 per IEC 60598 ensures that the enclosure is dust-tight and protected against jet streams of water from any direction without any harmful effects.



IP66 — UL Certified IP66 per IEC 60598 ensures that the enclosure is dust tight and protected against water projected in powerful jets without any harmful effects.



BSL — BioSafety Level (BSL-x) classifies the relative danger from biohazardous material to the surrounding people and environment. There are four biosafety levels (BSL1 – BSL4), with the highest number representing the greatest risk. Luminaires in each class are designed to provide the protections necessary for containing the risks associated with that level.



ISO 3 — Suitable for ISO 3, Class 1 Rated Rooms (FED-STD209E). Measures the number of particles equal to or greater than 0.5 mm in one cubic foot of air. The measurement must not exceed specified particle limits in order for the space to be considered a controlled 'clean room' environment.



ISO 5 — Suitable for ISO 5, Class 100 Rated Rooms (FED-STD209E). Measures the number of particles equal to or greater than 0.5 mm in one cubic foot of air. The measurement must not exceed specified particle limits in order for the space to be considered a controlled 'clean room' environment.



MIL STD 461G — Military Standards testing measurements cover both radiated and conducted electromagnetic emissions in addition to maximum allowable amounts of emitted energy based on both frequency range and field strength. Luminaires meeting MIL STD 461G pose the lowest possible likelihood of causing EMI-related issues.



NSF2 — An NSF2 Listing denotes that the luminaire has been evaluated for corrosion resistance, cleanability and the ability of exposed material to withstand normal wear. This supports the infection control standards established by healthcare facilities as it indicates that the luminaire is easy to sanitize.



NSF P442 — This protocol is a series of minimum requirements for the design, construction, performance and certifications of luminaires for cleanrooms. It requires ingress protection IEC 60529/60598 (IP-65) and NSF-2 Food Equipment certifications and a performance test for pressure decay resistance in which the sealed fixture is stressed with positive and negative pressure and checked to ensure that no leaks are present.



NSF P495 — NSF Indigo-Clean conforms to NSF P495-2018, a new standard of cleanliness that validates the disinfection of surfaces via narrow spectrum visible light (400nm – 420nm) in a controlled environment. The P495 certification demonstrates a statistically significant reduction of *Staphylococcus aureus* and/or *Clostridium difficile* endospores on clinically relevant surfaces, such as stainless steel and laminate. Light fixtures must also be NSF2 compliant.



UL/CUL Listed — The UL symbol signifies that Underwriter's Laboratory (UL) has determined that a manufacturer has demonstrated the ability to produce a product complying with UL's requirements with respect to specific risk, performance under specific conditions, compliance with regulatory codes and specified standards, or any other conditions as determined by UL.

Warranties

On behalf of our valued customers, Kenall promises to stand behind our luminaires. Our commitment to excellence enables us to offer a variety of product warranties, including the Kenall exclusive Peace of Mind Guarantee, 5-year LED and 10-year limited product warranty. For more detailed, product specific warranty information, please visit our website at www.kenall.com.



LED 5-year Warranty

Kenall offers a limited 5-year LED warranty on LED products. For complete warranty information, please visit us on the web at www.kenall.com.



Kenall's luminaires are expertly designed in our state-of-the-art, vertically integrated, static-controlled manufacturing facility in Wisconsin. This enables us to provide tight control over the entire development process from fixture design and engineering to full-fledged metal fabrication, paint, assembly and shipping. We also take great care in sourcing only the highest-quality components to assure optimal product performance.

Our products comply with the Buy American Act: manufactured in the United States with more than 50% of the component cost of US origin.





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