LUXIONA

CLEAN PROGRAM
Lighting Systems for Clean Rooms

troll

LUXIONA POLAND – THE LEADER OF CLEAN ROOMS

LUXIONA POLAND IS THE LEADER WHICH OFFERS LIGHTING SOLUTIONS FOR CLEAN PREMISES SUCH AS CLEAN ROOM IN:

- Medical facilities.
- Pharmaceutical industry.
- Chemical industry.
- Food industry.
- Precision and electronic industry

PRODUCTION PLANT IN JACENTOW

- The process of preparation and disinfection of the luminaries in line with ISO.
- Production realisation according to modern solutions and technologies.
- Broad machinery park.
- Production flexibility.
- Short realisation terms.
- Wide variety of products.
- Dedicated rooms for medical products manufacturing..

CERTYFICATE ISO 9001:2015

Range:

Designing and manufacturing the luminaries

CERTYFICATE ISO 14001:2015

CERTYFICATE ISO 13485:2012

Range:

Designing and manufacturing the luminaries for medical purpose


CSQ
MED
www.imq.it

CISQ is a member of
IQNet
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTYFIKAT NR.
CERTIFICATE N. **9124.LUXP**

ZAŚWIADCZA SIĘ, ŻE SYSTEM ZARZĄDZANIA JAKOŚCIĄ WDROŻONY PRZEZ
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

LUXIONA POLAND S.A.

Jacentów 167, 27 – 580 SADOWIE – POLSKA

JEDNOSTKI OPERACYJNE
OPERATIVE UNITS

Jacentów 167, 27 – 580 SADOWIE – POLSKA

JEST ZGODNY Z NORMĄ
IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2012

W NASTĘPUJĄCYM ZAKRESIE
FOR THE FOLLOWING ACTIVITIES

Projektowanie i wytwarzanie opraw oświetleniowych do zastosowań medycznych
Design and production of luminaries for medical purposes

Dalsze wyjaśnienia dotyczące zastosowania wymagań EN ISO 13485:2012 mogą być uzyskane poprzez konsultacje z organizacją
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

NINIEJSZY CERTYFIKAT POWINIEN BYĆ WYKORZYSTYWANY ZGODNIE Z ZASADAMI WYMIENIONYMI W REGULAMINIE CERTYFIKACJI SYSTEMÓW ZARZĄDZANIA
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATA: DATE:	PIERWSZA CERTYFIKACJA *FIRST CERTIFICATION*	BIEŻĄCE WYDANIE *CURRENT ISSUE*	WAŻNOŚĆ *EXPIRY*
	2014-04-03	2017-04-02	2020-04-02

The Organization shall obtain the certification according to EN ISO 13485:2016 within 2019/02/28; otherwise the validity of this certificate will expire
Organizacja powinna uzyskać certyfikację na zgodność z EN ISO 13485:2016 do 2019/02/28; w przeciwnym razie ważność tego certyfikatu wygaśnie

IMQ S.p.A. * VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Cimago

Only the English text is authentic

ACCREDIA

Ważność certyfikatu jest uzależniona poprzez coroczne audity kontrolne i recertyfikację
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

CISQ is the Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ
www.cisq.com


DEKRA

CERTIFICATE

LUXIONA
treil metalarte Sagelux

ISO 9001:2015

DEKRA Certification Sp. z o.o. hereby certifies that the company

LUXIONA POLAND S.A.

Scope of certification:
Design and production of lighting fittings.

Certified location:
PL – 27-580 Sadowie, Jacentów 167

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. W-A376717/B2/P/14001.

This certificate is valid from 2017-05-02 to 2020-05-01

Certificate registration no.: 320511036/3

DEKRA Certification Sp. z o.o. Wrocław, 2017-04-27

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

page 1 of 1


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treil metalarte Sagelux

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Design and production of lighting fittings.

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This certificate is valid from 2017-05-02 to 2020-05-01

Certificate registration no.: 440511035/3

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DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

page 1 of 1

PREMISE FOR PRODUCTION OF CLEAN LUMINARIESIN PRODUCTION PLANT IN JACENTOW:

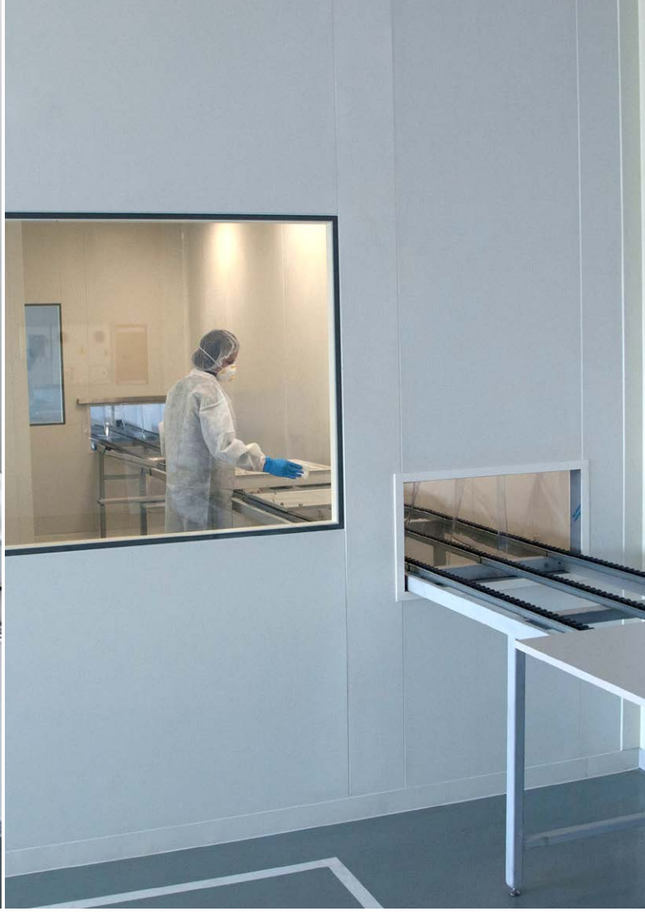
The premise of controlled environmental parameters especially pollution such as: dust, dustlike, bacteria, chemical vapours etc.

Depending on required atmosphere cleanliness of the CLEAN ROOMS are divided into classes in which amount and size of the pollution per cubic metre of atmosphere is defined(alternatively cubic foot).

Clean room premises can have dimensions of a production hall or even a production plant and a surface of few thousands square metres. These kinds of premises are commonly used during a production process of precise semiconductors, biotechnology and other fields in which even tiny pollution are critical parameter of technology.

The air is pumped inside the clean room through a special system of filters which eliminate subsequent fractions of pollution. The air inside the room is continuously filtered by set of HEPA filters in order to remove the pollution created inside. The employees entering and exiting the room have to do it through the air lock. The employees inside the clean room should wear all the time protective suits, masks and shoes. In less expensive solutions there is no air lock-the entrance is directly from antechamber where a protective suit is worn.

The devices inside a clean room have to be specially designed so as not to generate additional pollution. It applies also to luminaries which are produced in our production plant in specially prepared conditions.



NORM PN-EN 14644-1 - cleanliness class of rooms.
The basic document defining the level of pollution in a room concerning its size, is norm PN-EN 14644-1:2005 Clean rooms and connected with them controlled rooms.

The norm includes the classification of air quality in clean rooms and connected with them controlled environment in terms of particles concentration in the air and the methods of testing air quality as well as procedures defining the concentration of particles in the air.

The norm has been accepted by the European Committee for Standarization(CEN) and by Polish Committee for Standarization.

SPECIAL PROPERTIES OF CLEAN LUMINARIES SYSTEM

– Depending on the place where the luminary is applied there is possibility to equip the luminary in anti-reflective C56 which minimalizes the reflection of the laser light beam.
– Laminated matt pane with anti-reflective coating-SLMR.
– Hardened matt pane with anti-reflective coating-SLMR.
– Micro-prismatic diffuser with laminated anti-reflective pane-Micro PRM SLR.
– Micro-prismatic diffuser with hardened anti-reflective pane-Micro PRM SHR.

– Diffusers resistant to generally available disinfectants, ammonium salt, hydrogen peroxide, chlorine and UV radiation.
– Laminated matt pane-SLM.
– Hardened matt pane-SHM.
– Micro-prismatic diffuser with laminated pane-Micro-PRM SL.
– Micro-prismatic diffuser with hardened pane-Micro-PRM SH.

– Antibacterial coating preventing from micro-organisms development.

CRI 90

– The luminary is equipped with light source of the colour rendering index equal or higher than 90.

COLOUR RENDERING INDEX CRI

CRI (Colour Rendering Index) – colour rendering index, characterises the colour perception of illuminated objects.

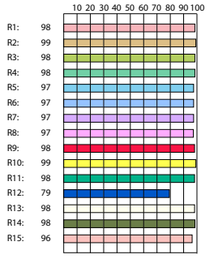
CRI accounts for numeric value of the range from 0 to 100.

CRI is an average component of emission spectrum from R1 to R15.

The scale of CRI – the higher index the better , more natural colour rendering is.

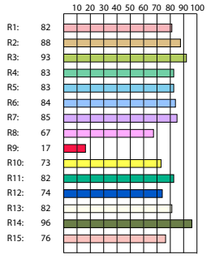
Example:
CRI = 100 – perfect light rendering colours (sunlight).
CRI = 93 – light accurately renders the colour.
CRI = 1 – the monochrome light.

CRI index of LUXIONA modules = 98,2

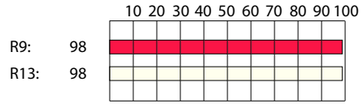


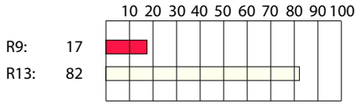
CCT	3926K
CRI	**98,2**
λp	642 nm
PFlicker	1,15 %

CRI index of competitors modules = 83,7



CCT	4129K
CRI	**83,7**
λp	447 nm
PFlicker	0,2 %





CRI = 98,2 LUXIONA's modules and simultaneous preservation of high components:
R9 – responsible for rendering "deep red" colour (colour of blood)
R13 – responsible for rendering „light orange" (colour of tissues)

CLEAN LUMINARIES ISO CRI90/MEDICAL PRODUCT

Legal characteristic of CLEAN luminary CRI90/MEDICAL PRODUCT:

- Product submitted and registered in the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.
- Product in compatible with basic requirements defined in directives of European Union: **Directive of the Council 93/42/EEC (MDD) and the Directive of European Parliament and the Council.**
- Fulfils the requirements defined in the bill of May 20th 2010 about Medical Products.
- Product tested and compatible with European norm **PN-EN 60601-1, PN-EN 60601-1-2** (Medical electric devices-overall safety requirements and basic technical requirements).

For medical products is in force:

- Individual production process in which the producer is obliged to ensure the conformity of the products during the design process and production with main requirements defined in the Regulation of the Health Ministry. Main requirements concern among other things the safety of the products and hazards related to product usage, which should be eliminated and restricted to the minimum.
- Restrictive procedures of quality control. In Poland the supervision and control over medical products is exercised by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The supervision depends on gathering and analy sing information concerning safety of the products and control of all entities which have direct or indirect influence on the medical product. The control of all entities includes all stages-from the design and manufacturing of medical product till the moment when the medical products is placed on the market or used.
- Specially dedicated technological line.

Application:

- Operating rooms.
- Intensive medical care rooms/OIOM.
- Rooms dedicated for laparoscopic and endoscopic treatments.
- Recovery rooms.
- Dermatological clinics.
- Blood sampling points.

Technical specification:

- Power of LED source from 25W to 124 W.
- Power of luminary from 28 W to 138 W.
- Luminous flux of LED sources from 3600 lm to 18000 lm.
- Colour rendering index CRI≥90.
- Colour temperature 4000 K.
- SDCM = 3.
- Lifetime of LED sources – 60000 h (L80/B10).
- Possibility to equip the luminary with LED module of green colour light (application: operating rooms for laparoscopic treatments).
- Available additional construction versions: INOX, NO FRAME.
- Antibacterial coating.
- Anti-reflective coating.
- IP65.
- IK08 or IK10 (INOX).

Available constructional models:

- Agat – recessed luminary dedicated for suspended ceilings of module structure.
- Rubin – surface mounted luminary.
- Topaz – luminaries for technical ceilings (luminaries opened from the top).

Available diffusers:

- Laminated, matt, anti-reflective pane-SLMR.
- Hardened, matt, anti-reflective pane-SHMR.
- Micro-prismatic diffuser with laminated anti-reflective pane-Micro PRM SLR.
- Micro-prismatic diffuser with hardened anti-reflective pane-Micro PRM SHR.

Available accessories:
Handle for pane opening (NO FRAME).

CLEAN CLASS LUMINARIES/FULL VALIDATION OF PRODUCTION PROCESS

Characteristics of CLEAN CLASS luminaries:

- Fulfil requirements of norm PN-EN ISO 14644-1 concerning I, II, III classes of room cleanliness. The norm defines air quality classification in terms of particles concentration in the air in clean rooms.
- Holds the certificate (COC) confirmed by accredited laboratory. It means that luminaries CLEAN CLASS can be used in clean rooms in accordance with norm PN-EN ISO 14644-1, and production process is repetitive and controlled in accordance with the Health Ministry Regulation of 1st October 2008 in the good manufacturing practice.
- Are subject of full validation of production process. Validation of the process aims to obtain the confirmation that it is useful for planned usage. The validation procedure takes into account particular aspects of good practices connected with assessed process.
- Production takes place in Clean Room premise where environmental parameters are controlled, especially pollution such as: dust, bacteria, chemical vapour etc.
- In line with European norm **PN-EN 60598-1** – Luminaries – Overall requirements and research.
- In line with GMP (good manufacturing practice). It is a set of standards applied in industrial production, specially in pharmaceutical industry, food industry and other fields of business activity.

Classes of cleanliness for rooms according to ISO norm:

- I class of room cleanliness – (rooms of possibly highest aseptic, minimal level of bacteria) acceptable bacteria concentration JTK 70 of bacteria/1m3 of air.
- II class of room cleanliness – (rooms of low bacteria level) acceptable bacteria concentration JTK 300 of bacteria/1m3 of air.
- III class of room cleanliness – (rooms of standard level of bacteria) acceptable bacteria concentration JTK 700 of bacteria/1m3 of air.

Technical specifications:

- Power of LED sources from 15 W to 124 W.
- Power of luminary from 17 W to 138 W.
- Luminous flux of LED sources from 2600 lm to 18000 lm.
- Colour rendering index CRI≥80 or CRI≥90.
- Colour temperature 3000 K or 4000 K.
- SDCM = 3 or SDCM = 5.
- Lifetime of LED sources – 60000 h (L80/B10).
- Possibility to equip the luminary with LED module of yellow light colour (application: pharmaceutical industry).
- Available additional constructional versions: INOX, NO FRAME, CORNER.
- Antibacterial coating.
- Possibility to equip the luminary with anti-reflective coating.
- IP65.
- IK08 or IK10 (INOX, CORNER).

Available constructional versions:

- Agat – recessed luminary dedicated for suspended ceilings of module structure.
- Rubin – surface mounted luminary.
- Topaz – luminaries for technical ceilings (luminaries opened from the top).

Available diffusers:

- Laminated matt pane – SLM.
- Hardened matt pane – SHM.
- Micro-prismatic diffuser with laminated pane – Micro-PRM SL.
- Micro-prismatic diffuser with hardened pane – Micro-PRM SH.

Diffusers resistant to generally available disinfectants, ammonium salt, hydrogen peroxide, chlorine and UV radiation.

Available accessories:
Handle for pane opening (luminary NO FRAME).

BEDSIDE LIGHTING PANEL BHU LINEMED W1/MEDICAL PRODUCT

Technical specifications:
- Power of LED source from 40 W to 75 W.
- Power of luminary from 43 W to 78 W.
- Luminous flux of LED sources from 1300/4400 lm to 2200/8800 lm.
- Colour rendering index CRI≥80.
- Colour temperature from 3000 K to 4000 K.
- SDCM = 3.
- Lifetime of LED sources – 60000 h (L80/B10).
- IP40.
- IK04.

Available diffusers:
- Opalized PMMA (polymethyl methacrylate) – PLX.

Wall mounting

BHU panel ensures:
- General lighting of the room by reflected light.
- Spot lighting for reading and examining.
- Night lighting.
- Power sockets 230 V.
- Teleinformatic sockets RJ45.
- Equipotentialisation socket.
- Push-button lighting switch.
- Medical gas outlet points.
- In-room paging system.

LUMINARIES CLEAN STANDARD

Technical specifications:
- Power of LED sources from 10 W to 124 W.
- Power of luminary from 13 W to 138 W.
- Luminous flux of LED sources from 1400 lm to 18000 lm.
- Colour rendering index CRI≥80 or CRI≥90.
- Colour temperature 3000 K or 4000 K.
- SDCM = 3 or SDCM = 5.
- Possibility to equip the luminaires with LED diodes providing the following colors of light: yellow, green, red, blue, RGB
- Lifetime of LED sources – 60000 h (L80/B10) or 50000 h (L70/B50).
- Available additional constructional versions: INOX, NO FRAME, CORNER, CLIP-IN.
- IP65 or IP54.
- IK08, IK04 or IK10 (INOX, CORNER, PRISON).

Available mounting models:
- Agat – luminaries dedicated to be mounted in suspended ceilings of modular and plasterboard structure.
- Rubin – surface mounted luminaries.
- Topaz – luminaries for technical ceilings (luminaries opened from the top).
- BHU – over-bed panels.
- Prison – surface mounted ceilings.
- Rubineo – luminaries to be mounted in recessed plasterboard ceilings.
- Limpio – recessed luminaries to be mounted in suspended plasterboard ceilings of modular structure.

Available diffusers:
- Laminated matt pane – SLM.
- Hardened matt pane – SHM.
- Opalized PMMA – PLX.
- Opalized polycarbonate – PC.
- Microprism – Micro-PRM/ Micro-Line.
- Microprismatic diffuser with laminated pane – Micro-PRM SL/Micro-Line SL.
- Microprismatic diffuser with hardened pane – Micro-PRM SH/Micro-Line SH.

Available accessories:
Handle for pane opening (NO FRAME luminaries).

RECESSED LUMINARY/**AGAT CLEAN LED**

* Luminary available in various models in terms of diffuser model or the value of the luminous flux.

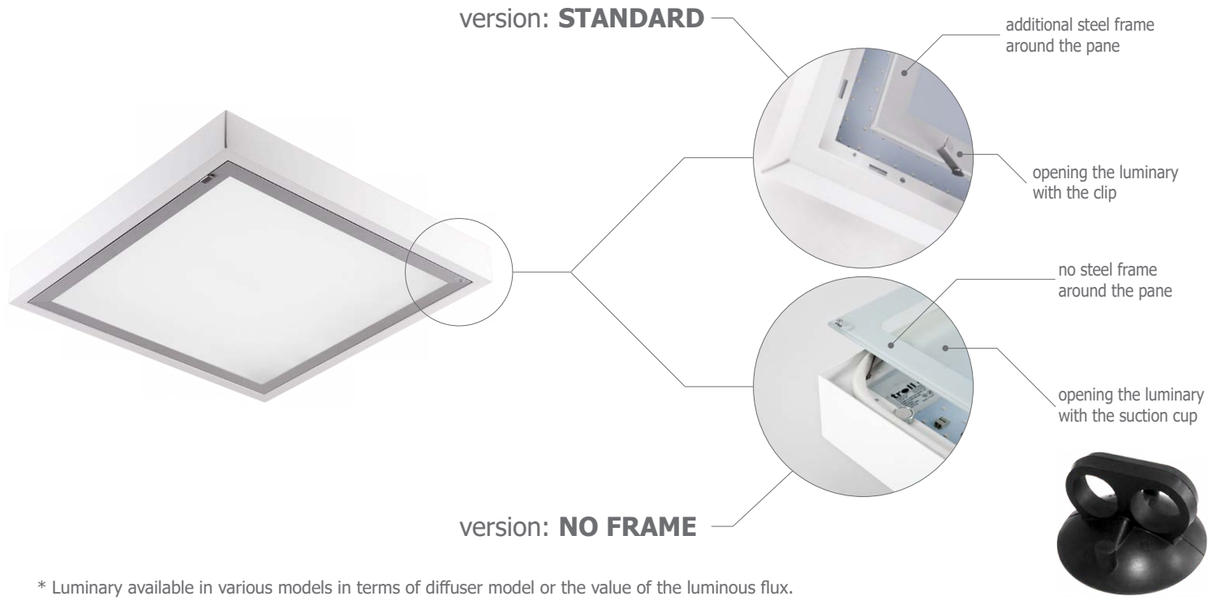
RECESSED LUMINARY/**TOPAZ ODG CLEAN LED**

SURFACE MOUNTED LUMINARY/**RUBIN CLEAN LED INOX**
(luminary made of stainless steel)

* Luminary available in various models in terms of the value of the luminous flux.

Technical specifications of the luminaries available on **www.luxiona.pl**

SURFACE MOUNTED LUMINARY/**RUBIN CLEAN LED**



* Luminary available in various models in terms of diffuser model or the value of the luminous flux.

BEDSIDE PANEL/**BHU LINEMED PREMIUM**

* Luminary available in various models in terms of diffuser model or the value of the luminous flux.

LUXIONA

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LUXIONA Poland is part of the Spanish LUXIONA Group, which for more than 80 years has been successfully operating on the international market of the lighting industry. The mission of LUXIONA Poland is to create complementary lighting solutions, in accordance with the most recent technologies as well as legal and social requirements. For that reason, an active team constantly works on innovative technical solutions, keeping in mind the need for saving energy and protecting the environment. The team does not cease to enhance the quality of our products and the efficiency of our services, permanently analyzing the needs of our Customers.

The LUXIONA Group, including LUXIONA Poland which continues to implement the Group strategy, specializes in the composition and creation of indoor and outdoor lighting systems, basing on the vast experts' experience and the broad scope of product brands. An integral part in the offer of LUXIONA Poland are comprehensive lighting solutions, which cover both the production and design services, in the widest sense of the word, delivered by high class designers and ready to meet the requirements of, among others: architectural spaces, areas in the so-called clean rooms, commercial surfaces etc. The LUXIONA Poland team specializes in implementing projects which require an individual approach and the application of modern technologies.