



Operating and Treatment Lights

NEXUS OL-01/OL-02

PROXY OL-03

ONYX TL-01



Operating light head

Modern Design

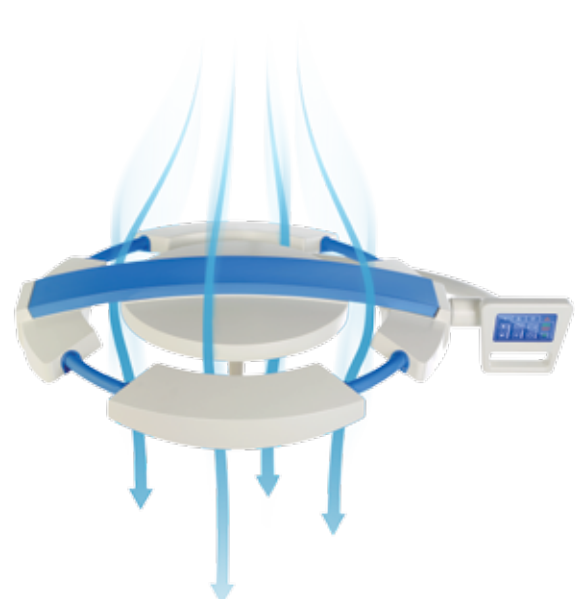
Operating lights INFIMED NEXUS and PROXY and treatment lights INFIMED ONYX with LED light source are distinguished by innovative technology and modern design.

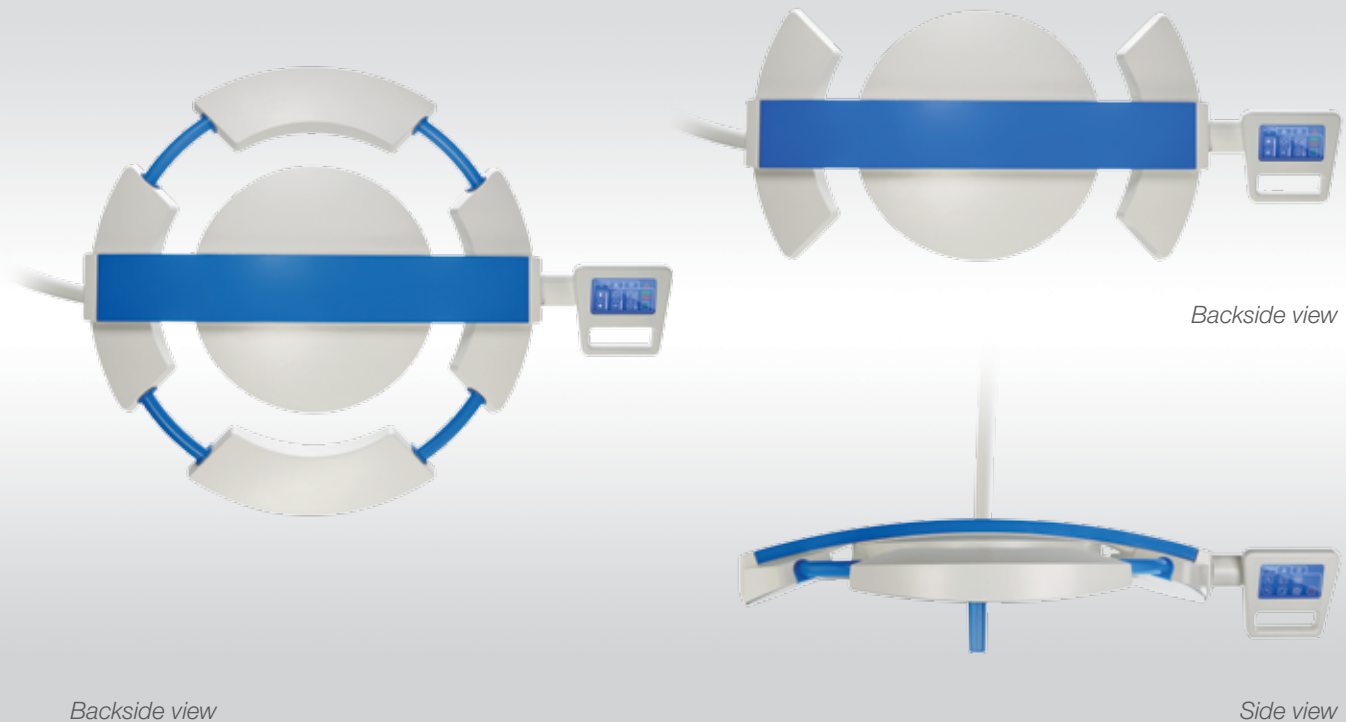
The little weight, ergonomic light heads as well as comfortable handles enable **easy and precise** set up and positioning of the operating light during surgery.

Waterproof, resistant to environmental factors design and smooth surfaces guarantees **ease of disinfection** and maintenance for perfect hygiene.

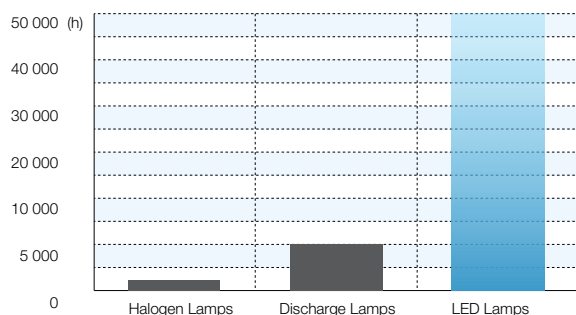
Ergonomic shape of the light minimizes disruption of **laminar airflow** in the operating theatre. The light head are closed construction, composed of solid, permanently assembled elements.

Flow-optimised light head





Economy



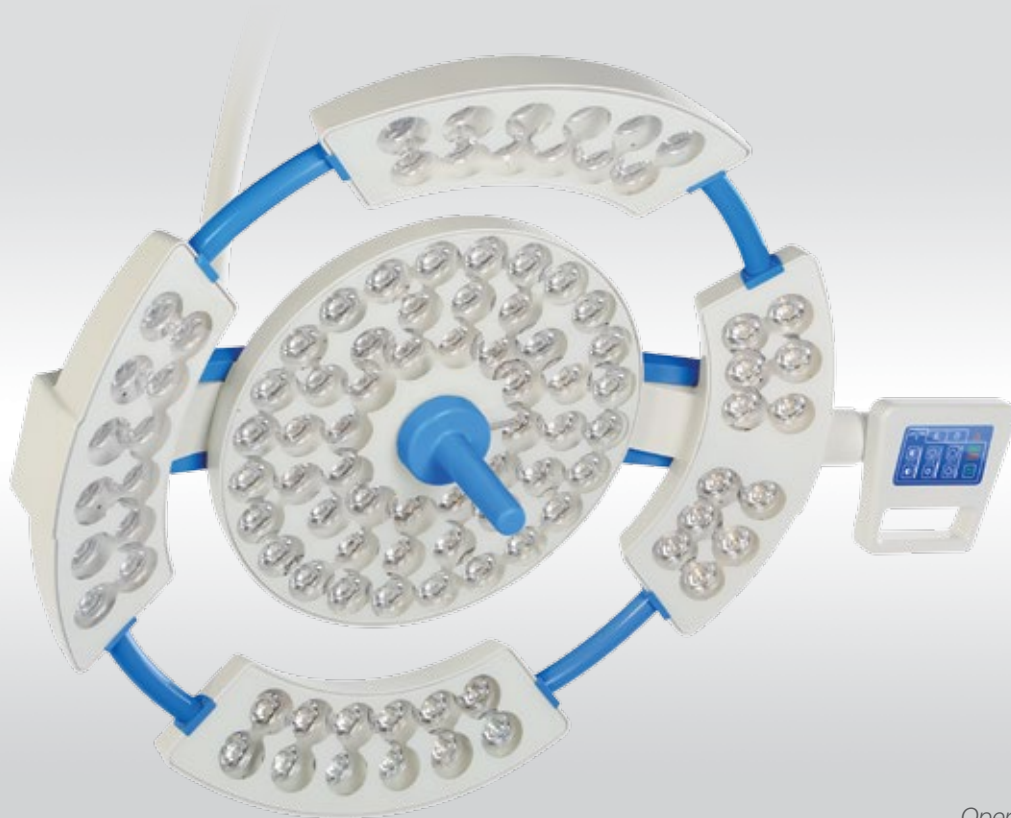
Low power consumption and high efficiency of LED light sources, provide measurable economic benefits by reducing maintenance costs of the operating theater.

Long lifetime of LED technology light sources, estimated at over 50,000 hours, several times exceeds conventional light sources. There is no frequent replacement of the light sources, significantly reducing maintenance and replacement costs.

Environmental Protection



LED light sources do not contain any heavy metals like lead or mercury which facilitate their future utilization. Aluminium, the main material of LED's can be efficiently recycled. LED light sources does not produce harmful UV radiation.



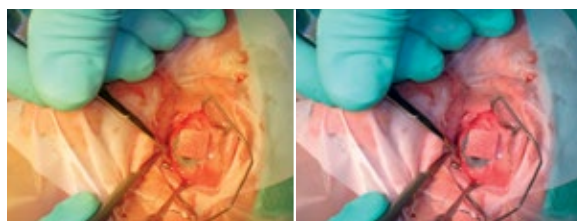
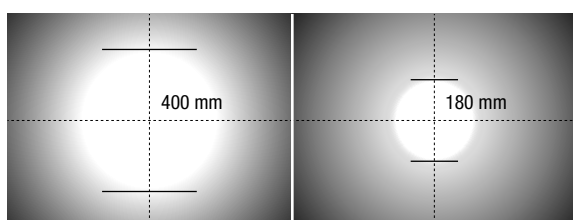
Operating light head

Efficiency

LED technology ensures **consistent light distribution** and enables almost shadow-free conditions.

Low heat radiation minimize the temperature increase in the surgeon's head area to imperceptible level.

High light intensity and color rendering index facilities surgeries of especially narrow and deep wounds. The illumination is electronically dimmed to provide optimum illumination of operating field. Together with wide range of **operating field size adjustment** optimal visual conditions are ensured.



Colour temperature adjustment enables changing the contrast of the observed tissue and reduces fatigue of operating surgeon, which affects the comfort and ergonomics of the medical staff.



Adjustable **endo light** function reduces eye fatigue in case of endoscopic procedures and reflections on the monitors.

OL-01 / OL-02 / OL-03 / TL-01



Operating light head

Parameter of operating light INFIMED NEXUS	OL-01	OL-02
Light intensity E_c	160 000 lx	130 000 lx
Light intensity adjustment	5 – 100%	5 – 100%
Color temperature T_c (without adjustment)	4300K (4800 K)*	4300K (4800K)*
Color temperature T_c (with adjustment)	(3700 – 5000 K)*	(3700 – 5000K)*
Light field diameter d_{10} at E_c	240 mm (180 – 400mm)*	240 mm (180 – 400mm)*
Working range	600 – 1500 mm	600 – 1500 mm
Illumination depth (L1+L2)	1300 mm	1300 mm
Color rendering index [Ra(1-8)]	> 95 (> 97)*	> 95 (> 97)*
Red color rendering index [R9]	> 95 (> 97)*	> 95 (> 97)*
Endo lighting with adjustable intensity	Green light	Green light
Temperature of light surface after 60 min	< 40,00 ° C	< 40,00 ° C
Increase of temperature near doctor's head	< 1,00 ° C	< 1,00 ° C
Power supply	90 – 250 V AC	90 – 250 V AC
Power consumption	110W	80W
Luminary head voltage	24 – 28V DC	24 – 28V DC
Average service life of the LEDs (h)	> 50 000	> 50 000
Class of protection of light head	IP54	IP54

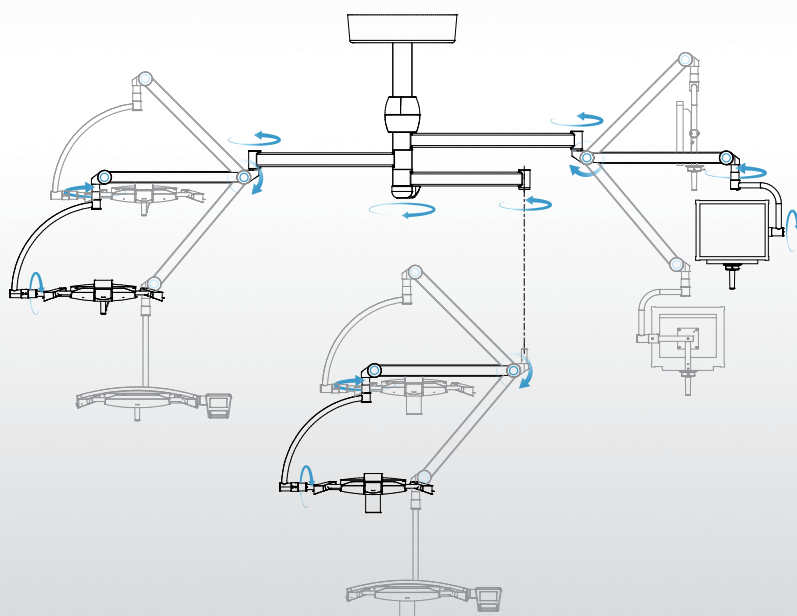
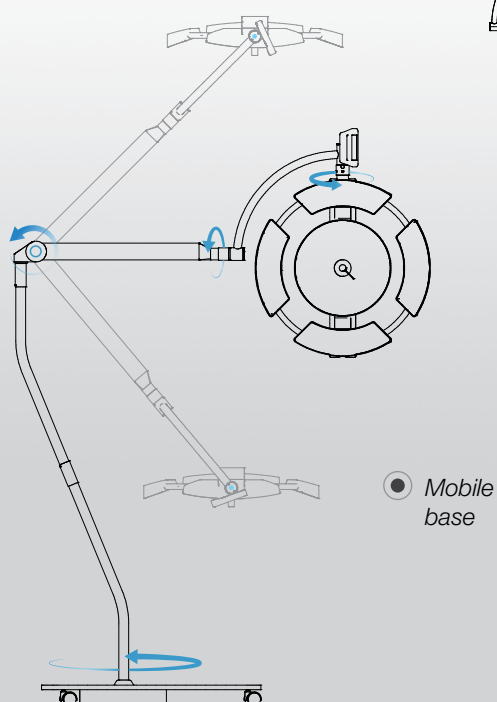
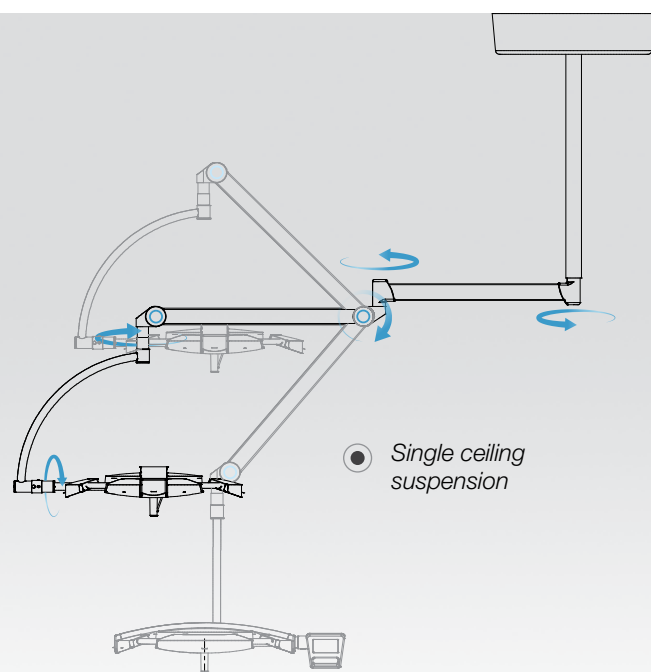
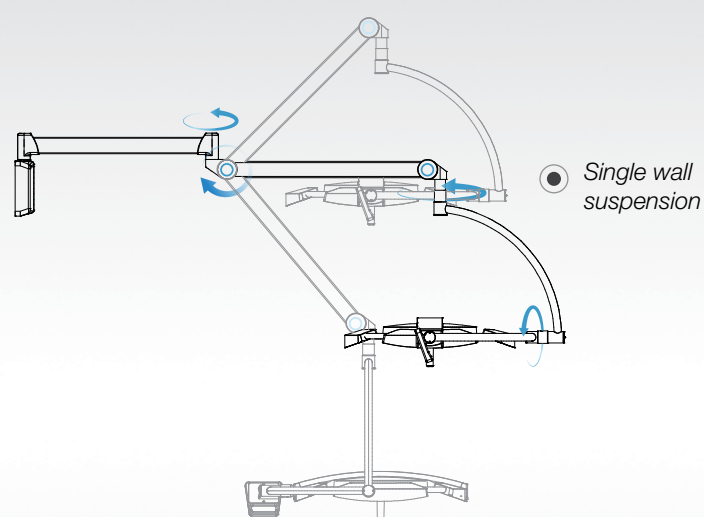
* additional options

Values are subject to a general industry tolerance of +/- 3%

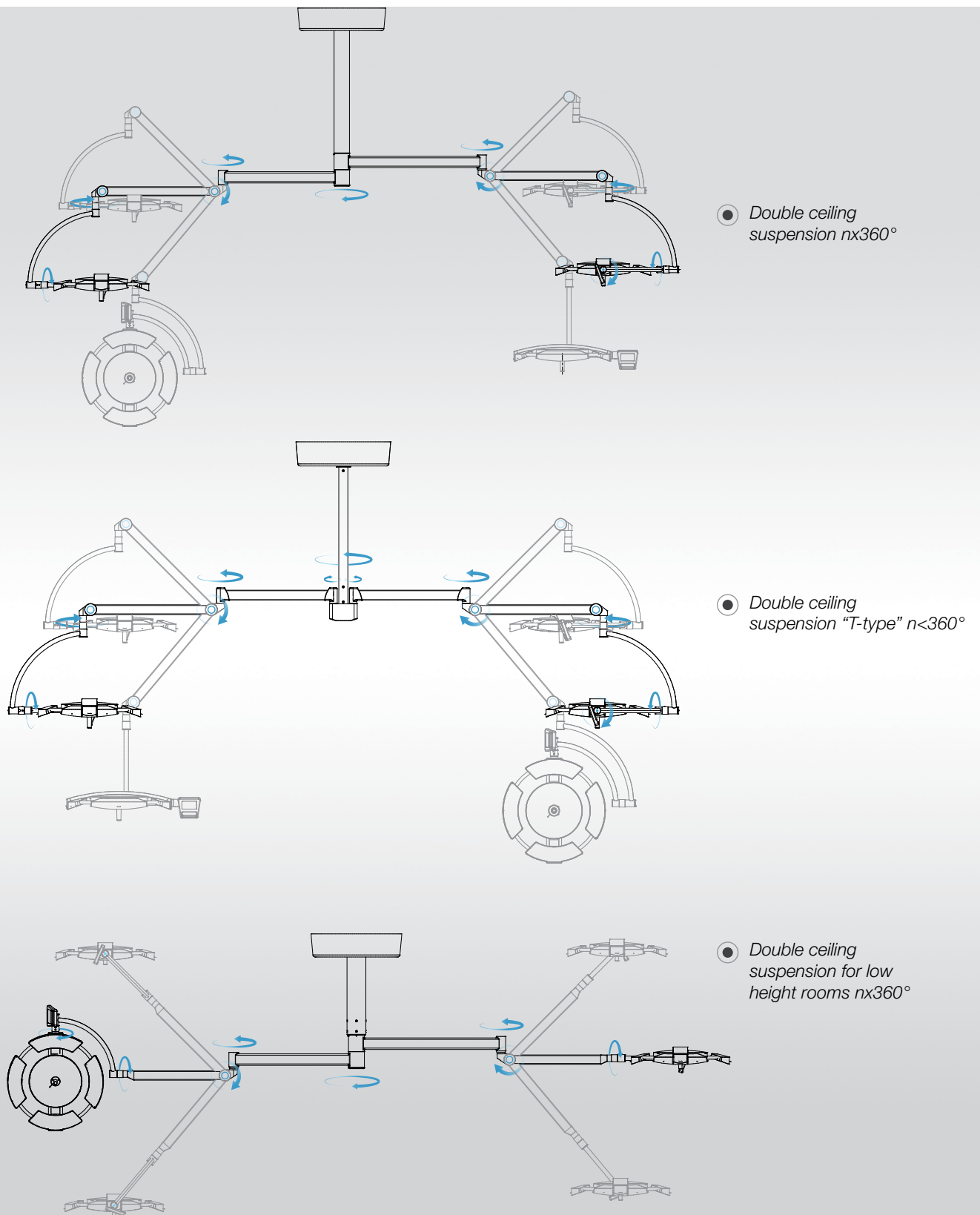
Configurations

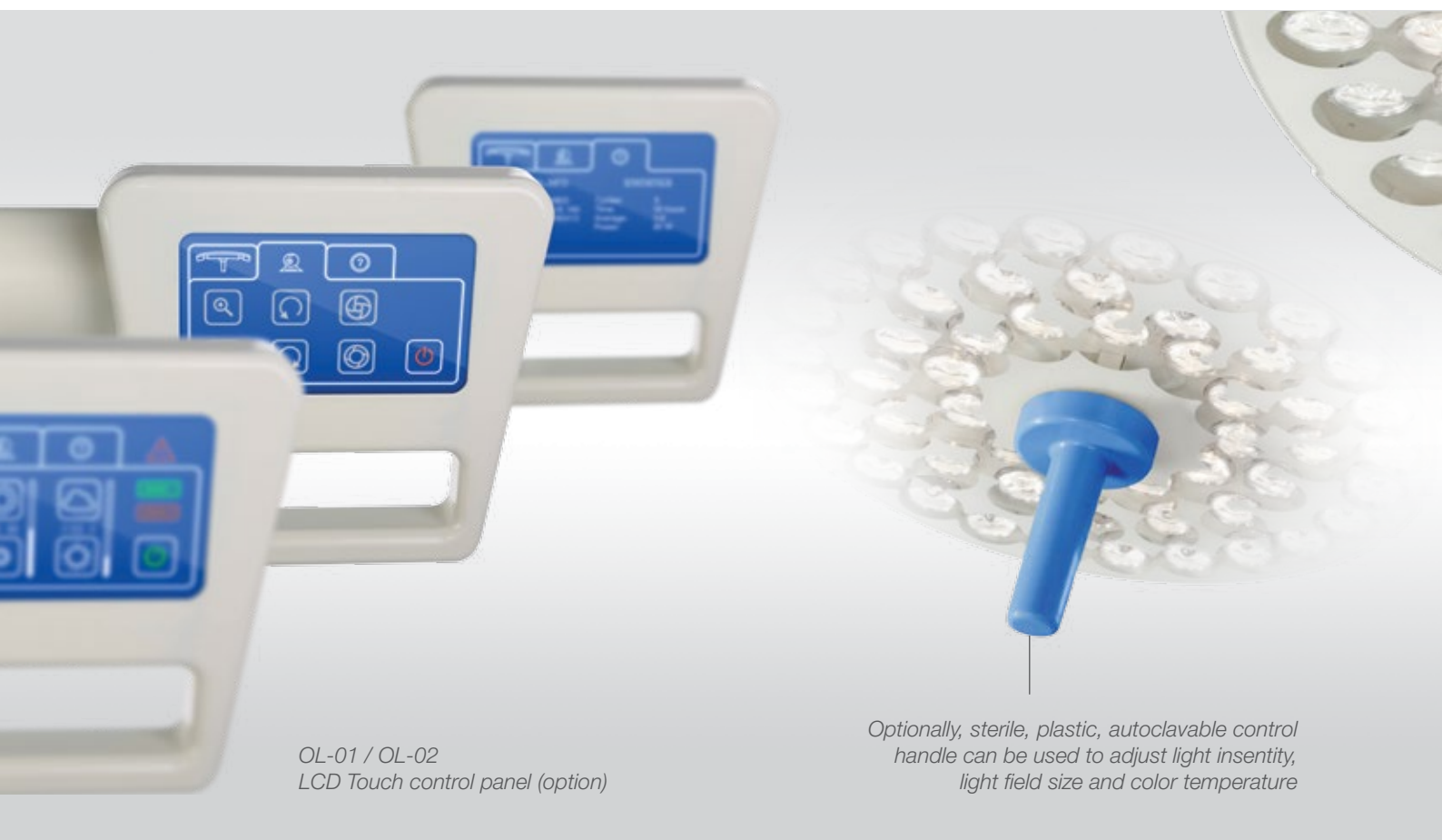
Operating lights INFIMED are available in ceiling suspensions (single, double, triple), single wall suspension and the mobile version equipped with the battery.

Examples of suspension configurations for operating lights:



Configurations





Controls And Communication

The sensor type control panel (standard) enables adjustment of:

- illumination intensity
- endoscopic illumination intensity
- switching ON/OFF
- light field size (option)
- color temperature adjustment (option)



The LCD type control panel (option) additionally enables adjustment of camera functions (zoom, iris manual, auto, focus manual and auto, stop image, rotation with lock >360 deg.) The LCD type control panel (option)

Additional functions

Measurement of the distance from operating area

The sensor in the light recognises the distance from the operating field and adjust the illumination intensity accordingly.

Intelligent shadow management

The sensor in the light perceives the surgeon head when it is directly under the light beam and brighten or dim specific LED's, in order to eliminate the shadows in the operating field.

Functions adjustment with sterile handle

Sterile, plastic, autoclavable control handle can be used to adjust 1-3 of following functions: light intensity, light field size and color temperature.

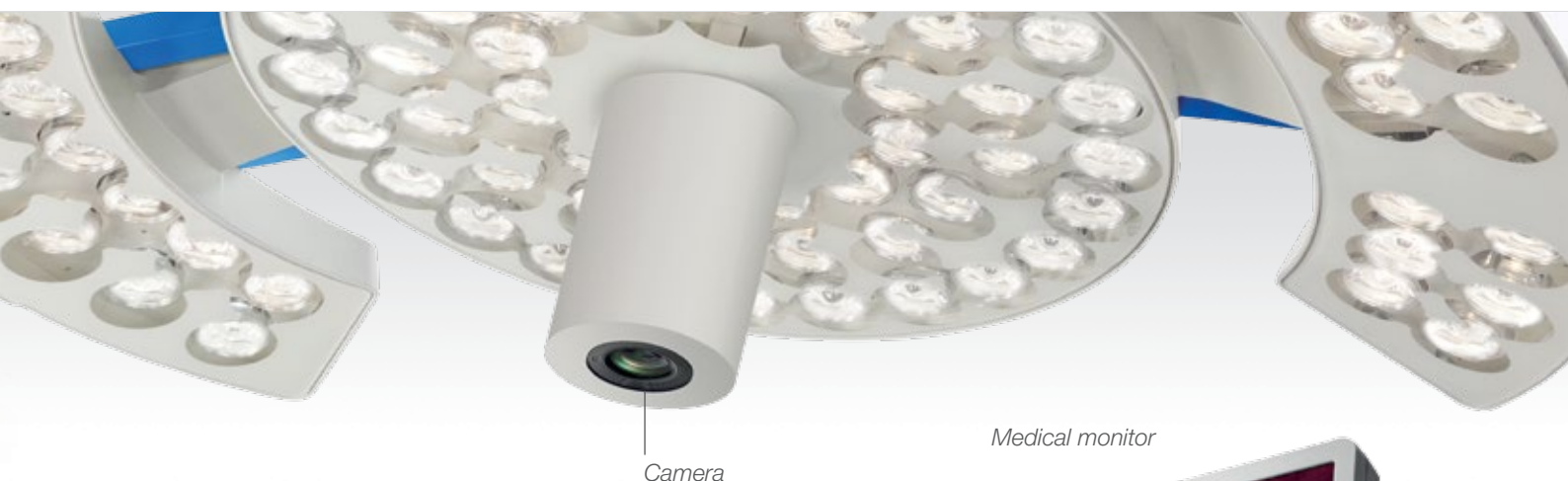
Synchronic adjustment of more light heads

Light heads adjustments can be synchronised: when adjusting any function of any light head, other light head (s) are adjusted simultaneously.

Infrared pointer

Infrared pointer shows the center of light beam.

Additional Equipment and Functions

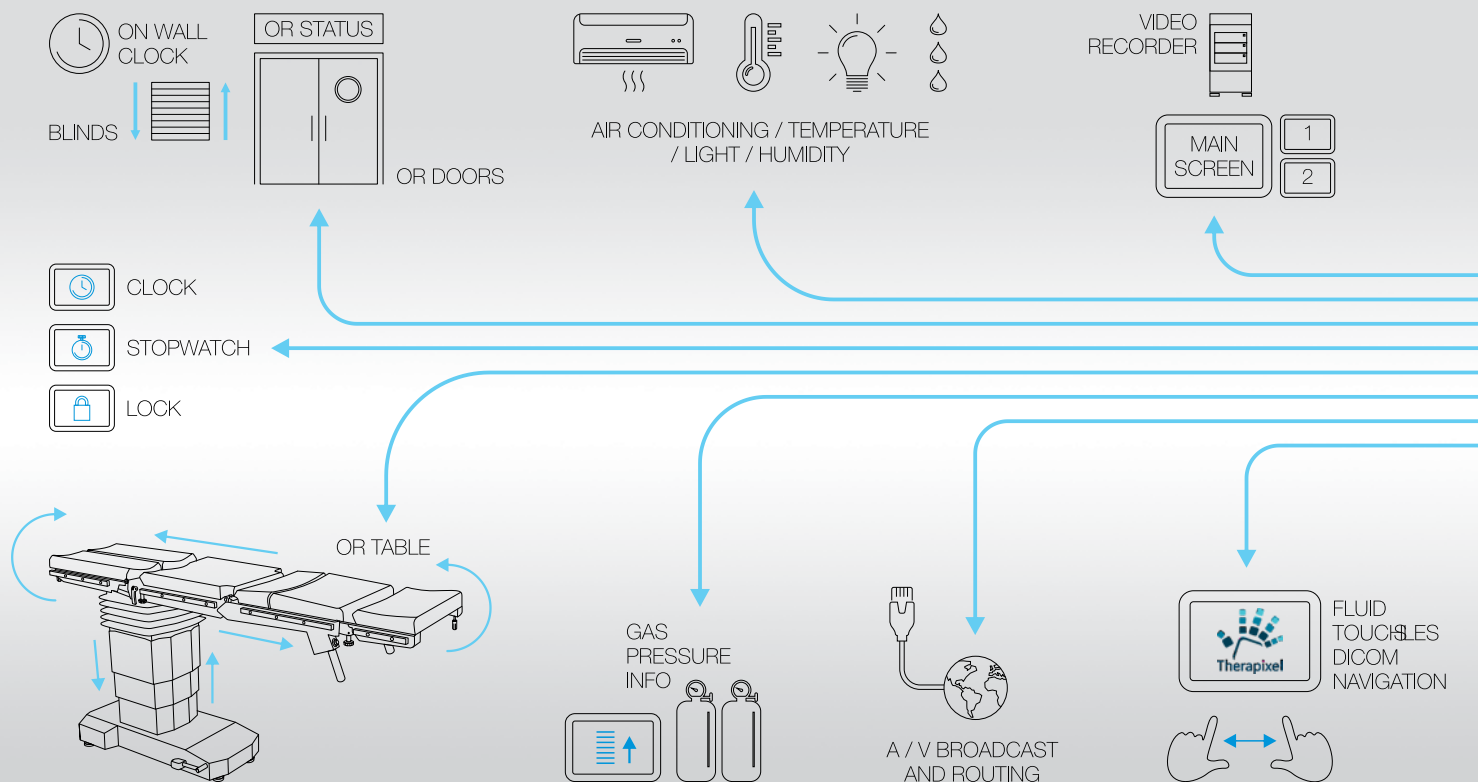


Integrated video system

Operating lights NEXUS OL-01 and OL-02 can be equipped with video camera, fixed in the center of the light. Optionally the lights can be delivered with standard sterile, plastic handle, to be exchanged into handle with camera in the future.
Sony camera, Full 1920 x 1080/30p High Definition, adjustable from keyboard.



Camera Specifications	Details
Image Device	1/2.8 type Exmor™ CMOS sensor
Effective Pixels	Approx. 2 million
Digital Zoom 20x	20x (200x with optical zoom)
Horizontal Viewing Angle	54.1° (wide end) to 2.9° (tele end)
Sync System	Internal
Electronic Shutter	1/2 to 1/10,000 s, 21 steps
White Balance	Auto
Focus System	Auto
Exposure Control	AE Control: Auto, Manual, Priority (shutter priority and iris priority)
Video Output	Details
Lens Value	20x Optical Zoom, f=4.7 mm (wide) ~ 94.0 mm (tele), f1.6 to f3.5
S/N Ratio More	More than 50 dB
Signal System	Signal System HD: 1080p/29.97, 1080p/25, 1080i/59.94, 1080i/50, 720p/50, 720p/29.97, 720p/25 SD: NTSC/PAL



Opera control system

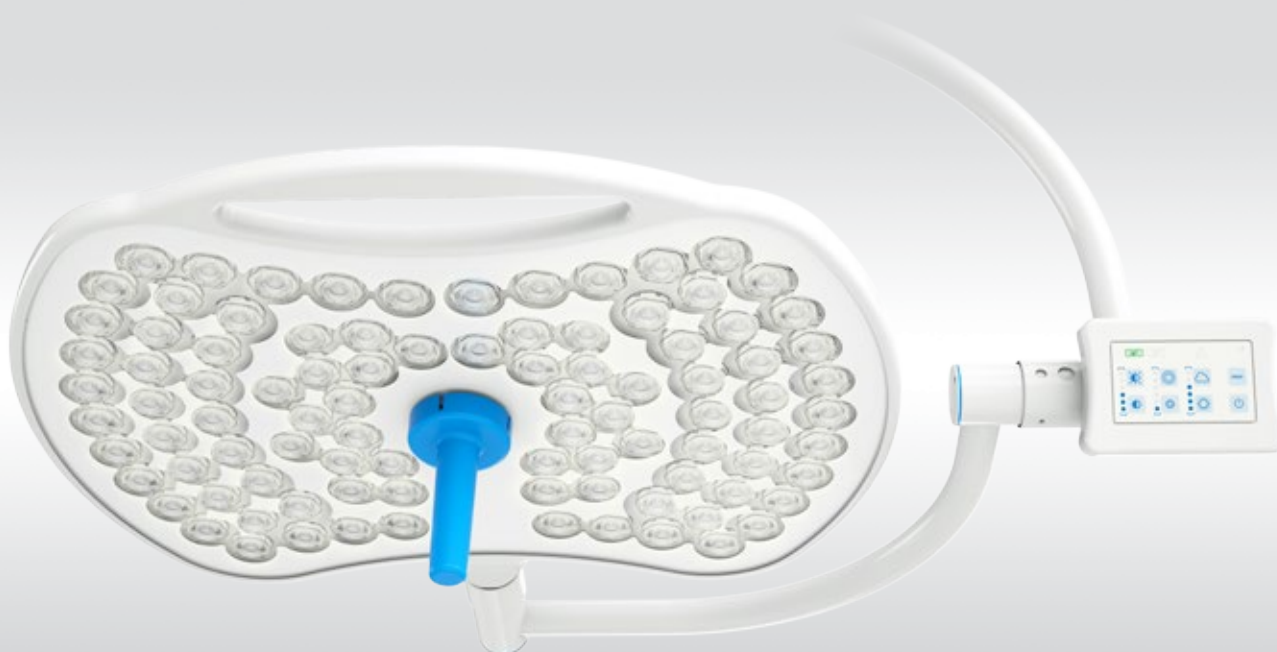
Provides better and easier control of the devices in the operating room from a single location. The system is very flexible, open, modular, can be adjusted to comply the client's expectations and requirements, accordingly to the above shown solutions. Can be operated from wall mounted control panel or wirelessly from mobile device.

The product is safe and secure and it is a certified Class I Medical Device manufactured in accordance with the ISO 9001, 13485 and other European standards. It provides a fully intuitive operation thanks to a simple and user-friendly interface, thereby minimizing the possibility of misuse and avoiding improper treatment operations.



Control System OPERA





OL-03 / Operating light head

Operating light PROXY

Is the economical solution of the modern operating light. The light head ensures perfect light parameters and full functionality, providing adjustments of light intensity, light field diameter and color temperature. Nevertheless it is delivered only in one version, without any options and modifications.

The light head cannot be equipped with the video camera fixed in the center, however can be provided separately on additional arm.

Neither the light cannot be controlled via OPERA control system.

All configurations mentioned on pages 6-7 are possible to implement.



OL-03



OL-03 / Backside view



OL-03 / Side view

Parameter of operating light INFIMED PROXY	OL-03
Light intensity E_c	160 000 lx
Light intensity adjustment	5 – 100%
Color temperature T_c (with adjustment)	3800 – 4800 K
Light field diameter d_{10} at E_c	230 mm – 400mm
Working range	700 – 1400 mm
Illumination depth (L1+L2)	1200 mm
Color rendering index [Ra(1-8)]	> 96
Red color rendering index [R9]	> 93 (> 95)*
Endo lighting with adjustable intensity	Green light
Temperature of light surface after 60 min	< 40,00 ° C
Increase of temperature near doctor's head	< 1,00 ° C
Power supply	90 – 250 V AC
Power consumption	80 W
Luminary head voltage	24 – 28V DC
Average service life of the LEDs (h)	> 50 000
Class of protection of light head	IP54

* additional options

Values are subject to a general industry tolerance of +/- 5%


Treatment light ONYX, 60 000 lx

Lights INFIMED ONYX TL-01

Lights ONYX are usually used in operating and procedures rooms, intensive care, neonatology units, induction rooms, dentist, dermatology, gynecology cabinets, veterinary cabinets, dissection rooms. They are available with different levels of illumination intensity. Treatment lights can have 30 000 or 60 000 lx. The light having 100 000 lx, optionally with field size adjustment can be used as minor operating light.

Light intensity and optional light field size adjustment are adjustable by control panel.

Lights INFIMED ONYX are available in single ceiling, double ceiling, single wall suspensions and mobile version with or without the battery.


Control panel (standard)

Control panel (option)


TL-01



Minor operating light ONYX, 100 000 lx
with field size adjustment.



Treatment light ONYX, 30 000 lx

Parameter	INFIMED ONYX 60 000/100 00 lx	INFIMED ONYX 30 000 lx
Light intensity Ec	60 000 lx / (100 000 lx)*	30 000 lx
Dimming range	10 – 100%	10 – 100%
Color temperature Tc	4300K (4800K)*	4300K (4800K)*
Light field size d10 at Ec	260 mm / (240 – 340 mm)*	180 mm
Color rendering index [Ra(1-8)]	> 92 (> 95)*	>92 (>95)*
Red color rendering index [R9]	(>90)*	> 90 (> 92)*
Temperature of light surface after 60 min	< 40,00° C	< 40,00° C
Increase of temperature near doctor's head	< 1,00° C	< 1,00° C
Power supply	90 – 250 V AC	90 – 250 V AC
Power consumption (± 10%)	50W	20W
Luminary heads voltage	24 – 28V DC	24 – 28V DC
Life cycle of the lights	> 50 000	> 50 000
Class of protection of light head	IP54	IPX2

* additional options

Values are subject to a general industry tolerance of +/- 5%



European Union
European Regional
Development Fund



For special requirement of the customer it is possible to produce the product with changed technical parameters which do not diminish its safety.

The details given in this catalogue are correct at the time of going to press. Infimed Sp. z o.o., however, reserves the right to improve shown equipment.

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NIP 553-251-29-67
REGON 243274947
KRS 0000463933

Sąd Rejonowy w Bielsku-Białej, VIII Wydział
Gospodarczy Krajowego Rejestru Sądowego.
Wysokość Kapitału Zakładowego: 500 000 PLN

bank Bank Spółdzielczy
w Węgierskiej Górze
SWIFT POLUPLPR

78 8131 0005 0016 2492 2000 0010 PLN
PL02 8131 0005 0016 2492 2000 0020 EUR
PL23 8131 0005 0016 2492 2000 0030 USD



www.infimed.pl



Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

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Tel/fax +48 33 861 40 96

e-mail: office@infimed.pl

We hereby declare for our own responsibility, that

Medical device: Operating light

Name: PROXY

Type: OL-03

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

covered by Technical file no 1.0, date 12.2016

Inspection documentation of device: Report of final inspection no 17.3.1.10

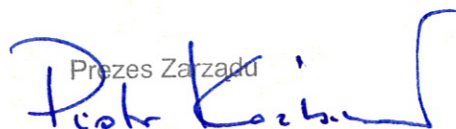
fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



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(4)

Prezes Zarządu

Piotr Koźbial

Place and date: Żywiec 02.12.2016

Name and surname:



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List of all harmonised standards required by Directive 93/42/EEC:

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-41:2009 + A11:2011	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



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SWIFT POLUPLPR

78 8131 0005 0016 2492 2000 0010 **PLN**
PL02 8131 0005 0016 2492 2000 0020 **EUR**
PL23 8131 0005 0016 2492 2000 0030 **USD**

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Infimed Sp. z o.o.
ul. Kabaty 1
34-300 Zywiec
Poland

has established and applies a quality management system for medical devices
for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-02-13
Certificate Registration No.: SX 60136721 0001
An audit was performed. Report No.: 26300455 001
This Certificate is valid until: 2022-01-31

Certification Body



Date 2019-02-13

Maciej Sciera
Maciej Sciera



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60136721 0001
Report No.: 26300455 001

Organization: Infimed Sp. z o.o.
ul. Kabaty 1
34-300 Żywiec
Poland

Scope:

Design and development, production, distribution, installation and servicing of surgical and treatment luminaires, luminaires for diagnosis, devices for patient positioning and transport with related equipment, medical furniture, modular room systems for operating theatre as well as software working in combination with related infrastructure for managing and integration of equipment and medical devices in operating room

Certification Body



Date: 2019-02-13

Maciej Sciera



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 13761



Certificate Holder: **INFIMED Sp. z o.o.**
ul. Kabaty 1
34-300 Żywiec
Poland



Scope: Design and development, production, distribution, installation and servicing of surgical and treatment luminaires, luminaires for diagnosis, devices for patient positioning and transport with related equipment, medical furniture and metal products, modular rooms systems for operating theatre, control systems of operating theatre equipment

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2019-10-20 until 2022-10-19.

2019-10-09

Grzegorz Guabka

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