CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

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.

CSQ

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9124.RMS2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di dispositivi medici elettromedicali di illuminazione per sala operatoria e per osservazione
Design and manufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2001-11-15	2019-09-12	2022-11-14

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

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.08.05 12:17:40 EEST
Reason: MoldSign Signature
Location: Moldova

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CISQ is a member of

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THE INTERNATIONAL CERTIFICATION NETWORK

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CERTIFICATO N. / *CERTIFICATE N.* **9120.RMS1**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di dispositivi medici elettromedicali di illuminazione per sala operatoria e per osservazione e apparecchi tecnici di illuminazione
Design and maufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis and technical lighting devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2001-11-15	2019-09-12	2022-11-14

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

***CISQ/IMQ** has issued an IQNet recognized certificate that the organization:*

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

has implemented and maintains a

Quality Management System

for the following scope:

Design and maufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis and technical lighting devices

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: ***2019 - 09 - 12***

Expires on: ***2022 - 11 - 14***

This attestation is direcly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 20641

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

PENTALED
N- SERIES

MANUAL DIAMETER ADJUSTMENT

The Pentaled N-series made a breakthrough in medical lighting. It has been the first LED surgical light ever displayed to the public.
The manual focalization inside the sterile area grants a precise and immediate control of the light field. The Focus function is activated by the surgeon rotating the sterile central handle.

PENTALED 63 N
PENTALED 30 N

-CEILING DOUBLE
Pentaled 30N+30N
(code PENTA30N+30N)

-MOBILE
Pentaled 30 N mobile
(code PENTA30NPI)

-CEILING SINGLE
Pentaled 30N ceiling
(code PENTA30NSO)

-WALL MOUNTED
Pentaled 30N
(code PENTA30NPA)

-CEILING DOUBLE
with satellite Pentaled 63N+30N
(code PENTA63N+30N)

-CEILING DOUBLE
Pentaled 63N+63N
(code PENTA63N+63N)

-CEILING SINGLE
Pentaled 63N ceiling
(code PENTA63NSO)

Performances

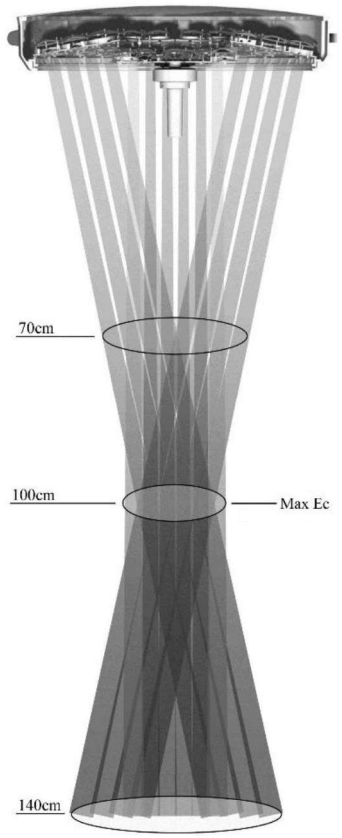
	63 N	30 N
Light intensity at 1 m distance (Ec)	160.000 lux	160.000 lux
Light head diameter	63 cm	40 cm
Color temperature (2 selections)	4.500 - 5.000K	4.500 - 5.000K
Color rendering index (CRI)	96 Ra	96 Ra
Diameter adjustment	Manual	Manual
d10 light field diameter where illuminance reached 10% of Ec	260 mm	205 mm
Light field diameter adjustable from-to	160 - 300 mm	140 - 280 mm
Depth of illumination IEC 60601-2-41 (L1+L2) at 60%	560 mm	650 mm
Depth of illumination IEC 60601-2-41 (L1+L2) at 20%	1080 mm	1150 mm
Total radiated energy Ee where the illuminance reaches max level	580 W/m²	580 W/m²
Ratio between radiated energy Ee and illuminance Ec	3,68	3,67
Average LED life	> 60.000 hours	> 60.000 hours
Control of the illuminance	20 - 100 %	20 - 100 %
Electrical absorption	60 W - 67 VA	52 W - 60 VA

Regulation (EU) 2017/745 of the European Parliament and of the Council, of 05th April 2017 – Norm IEC 60601-2-41

MAIN FEATURES

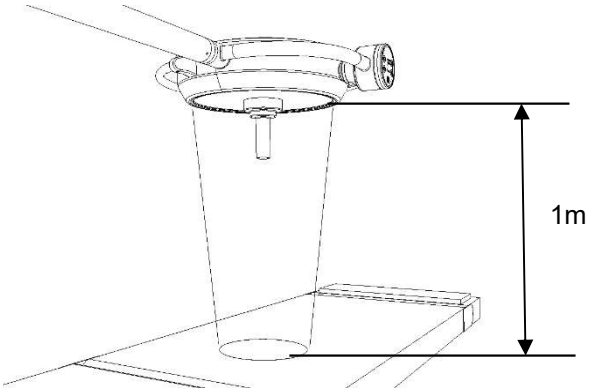
ACCESSORIES

(**PENTALED 63N** ONLY)



RECOMMENDED WORK DISTANCE

To optimize light intensity, the product is best used at a distance of 1m.



The Product nevertheless also ensures a good light intensity at a distance between 70cm and 140cm.

5.4.1 Brakes for mobile version

The mobile version has 4 wheels with pedal brake. This are used to block the Product in the required position.

Press the brake pedal with your foot, without applying too much pressure.

Risk of damaging pedal.

Do not kick the brake pedal and do not press continuously once the stop position has been reached.

To disengage the brake, lift the pedal with your foot.

RIMSA

DICHIARAZIONE CE DI CONFORMITA' DEL COSTRUTTORE

La società: **RIMSA P. LONGONI S.r.l.**
Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) - ITALIA

dichiara sotto la propria responsabilità che i Dispositivi Medici prodotti nell'anno 2020:

Modello*:* **PENTALED 30N**

Versioni	mod. Pentaled 30N SO (dispositivo a soffitto)
	mod. Pentaled 30N PI (dispositivo a piantana)
	mod. Pentaled 30N PA (dispositivo a parete)
	mod. Pentaled 30N +30N (dispositivo a soffitto doppio)

costruiti da RIMSA P.LONGONI S.r.l., sono conformi:

- *all'Allegato VII della Direttiva 93/42/CEE del 14/05/1993, applicata in Italia dal Decreto Legislativo N.46 del 24 Febbraio 1997 e successive varianti (inclusa la Direttiva 2007/47/CE del 05/09/2007, applicata in Italia dal Decreto Legislativo N.37 del 25 Gennaio 2010) e alle seguenti norme:*

  - IEC 60601-1 (Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali)
  - IEC 60601-2-41 (Parte 1: Norme particolari relative alla sicurezza fondamentale e alle prestazioni essenziali delle lampade scialitiche per uso chirurgico e per la diagnosi)
  - IEC 60601-1-2 (Parte 2: Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali- Norma collaterale: Compatibilità elettromagnetica – Prescrizioni e prove)

  - Classificazione in riferimento all'articolo 9 e allegato IX della Direttiva 93/42/CEE e 2007/47/CE
    Durata: Breve termine (Allegato IX,Par.1 "Definizioni", art.1, comma 1.1)
    Descrizione: Disp. Medico non invasivo (Allegato IX, Par.1 "Definizioni", art.1, comma 1.2)
    Disp. Medico attivo (Allegato IX, Par.1 "Definizioni", art.1, comma 1.4)
    CLASSE: Classe I (Allegato IX, par.3 "Classificazione", art.3, comma 3.3, Regola 12) e
    (Allegato IX Par.3 "Classificazione", art.1, comma 1.1 Regola 1)
  - Riferimento fascicolo tecnico Cod. RIM-FT008.
  - La valutazione di conformità è sviluppata in riferimento all'articolo 11 della Direttiva 93/42/CEE e 2007/47/CE.

Il Sistema Qualità di RIMSA è conforme alle norme UNI EN ISO 9001 e UNI CEI EN ISO 13485 ed è certificato da CSQ (certificato CSQ n.9120.RMS1 e 9124.RMS2).

Seregno, 07/01/2020

Luogo e data

Timbro e firma del Consigliere Delegato
(Paolo Longoni)

RIMSA

MANUFACTURER'S DECLARATION OF CONFORMITY CE

The company **RIMSA P. LONGONI S.r.l.**
Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) - ITALY

declares on its own responsibility that the Medical Devices made in the year 2020:

Model: **PENTALED 30N**

Versions	mod. Pentaled 30N SO (ceiling device)
	mod. Pentaled 30N PI (mobile device)
	mod. Pentaled 30N PA (wall device)
	mod. Pentaled 30N+30N (double-ceiling device)

constructed by RIMSA P.LONGONI S.r.l., conforms:

- *to the Attachment VII of the 93/42/EEC Directive of May 14th 1993, and subsequent variations (including the 2007/47/EC Directive of September 5th 2007); moreover, it is in conformity with the following safety regulation:*

  - IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
  - IEC 60601-2-41 (Part 2: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis)
  - IEC 60601-1-2 (Part 1: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility - Requirements and tests)

  - Classification with reference to article 9 and Attachment IX of 93/42/EEC Directive and 2007/47/EC
    Duration : Short term (Annex IX, Par.1 "Definitions", art.1, sub-section 1.1)
    Description: Non invasive Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.2)
    Active Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.4)
    Class: Class I (Annex IX, Par.3 "Classification", art.3, sub-section 3.3, Rule 12)
    (Annex IX, Par.3 "Classification", art.1, sub-section 1.1, Rule 1)
  - Reference to technical file Code RIM-FT018.
  - The conformity assessment is developed in reference to article 11 of the 93/42/EEC Directive and 2007/47/EC.

RIMSA Quality System conforms to the UNI EN ISO 9001 and UNI EN ISO 13485 regulations and is certified by the CSQ (certified CSQ n.9120.RMS1 and 9124.RMS2).

Seregno, 07/01/2020

Place and date

RIMSA - P. LONGONI S.r.l.

Mark and sign of Managing Director
(Paolo Longoni)