

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

ACEM S.p.a.

Via della Tecnica, 29

IT - 40050 Argelato (BO)



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

Design and manufacturing of lamps and luminaires for medical use.

Through an Audit, Report No. 7979790010FS07, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0541602**.

This Certificate is valid from 2022-05-31 to 2025-06-04.

The reference date for all the next audits is (day-month): 27-04.

Milan, 2022-05-31. First Certification: 2010-06-04

The certification responsible: Daniele Ricchi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of
the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



SGQ N° 083 A



Management
System
ISO 13485:2016

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

www.tuvitalia.com

 **TÜVRheinland®**

DICHIARAZIONE DI CONFORMITÀ



ACEM

ACEM SpA

Via della tecnica, 29
40050 Argelato (Bologna) – Italia

S.p.A.

Dichiara sotto la propria responsabilità che il prodotto,

Tipologia: Lampada scialitica secondaria per chirurgia

Nome: STARLED3 NX , STARLED3 NX - satellite ,

Nelle versioni: SOFFITTO, PARETE, TROLLEY, TROLLEY ABPS

sono conformi ai requisiti della **Direttiva Dispositivi Medici 93/42/EEC;**

sono classificati secondo l'allegato IX - regola 1, come,

Classe: I

e sono conformi alle norme armonizzate:

EN-60601-1:2007-05 e Variante EN 60601-1/A1:2014-09

“Apparecchi elettromedicali.

Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali”.

EN-60601-2-41:2011-10 e Variante EN 60601-2-41/A1:2016-12

“Apparecchi elettromedicali.

Parte 2: Norme particolari relative alla sicurezza fondamentale e alle prestazioni essenziali delle lampade scialitiche per uso chirurgico e per la diagnosi”.

e alla Direttiva:

2015/863/CE RoHS3

“Riduzione dell'uso di sostanze pericolose nelle apparecchiature elettriche ed elettroniche”.

Luogo e data:

Argelato, 15 Gennaio 2018

Timbro e firma direzione generale


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CE DECLARATION OF CONFORMITY

ACEM

ACEM SpA

Via della tecnica, 29
40050 Argelato (Bologna) – Italia

S.p.A.

Declare under its sole responsibility, that the product,

Type: Minor Surgical Luminaire

Name: STARLED3 NX , STARLED3 NX - satellite

Versions: CEILING, WALL, TROLLEY, TROLLEY ABPS

comply with the requirements of the **Medical Devices Directive 93/42/EEC**;
are classified according annex IX - rule 1, as,

Class: I

and comply with harmonized standards:

EN-60601-1:2007-05 and Variant EN 60601-1/A1:2014-09

“Medical electrical equipment.

Part 1: General requirements for basic safety and essential performance”.

EN-60601-2-41:2011-10 and Variant EN 60601-2-41/A1:2016-12

“Medical electrical equipment.

Part 2: Particular requirements for basic safety and essential performance of surgical luminaires
and luminaires for diagnosis”.

and with Directive:

2015/863/CE RoHS3

“Restriction of the use of certain hazardous substances in electrical and electronic equipment”.

Place and Date:

Stamp and general manager signature

Argelato, 15th January 2018.


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DECLARACION DE CONFORMIDAD



ACEM

ACEM SpA

Via della tecnica, 29
40050 Argelato (Bologna) – Italy

S.p.A.

Declara bajo de su responsabilidad, que el producto,

Tipo: Luminaria menor de cirugía

Nombre: STARLED3 NX , STARLED3 NX - satélite

Versiones: TECHO, PARED, TROLLEY, TROLLEY ABPS

Cumple a los requisitos de la **Directiva Dispositivos Medicos 93/42/EEC**;
clasificado de acuerdo con el anexo IX - regla 1, como,

Class: I

Y cumple con las normas armonizadas:

EN-60601-1:2007-05 y Variante EN 60601-1/A1:2014-09

“Equipos electromédicos.

Parte 1: Requisitos generales para la seguridad básica y funcionamiento esencial”.

EN-60601-2-41:2011-10 y Variante EN 60601-2-41/A1:2016-12

“Equipos electromédicos.

Parte 2: Requisitos particulares para la seguridad básica y funcionamiento esencial de las luminarias quirúrgicas y las luminarias para diagnóstico”.

y cumple con la Directiva:

2015/863/CE RoHS3

“Reducción del uso de sustancias peligrosas en los aparatos eléctricos y electrónicos”.

Luego y fecha:

Sello y firma del gerente general

Argelato, 15 de Enero 2018.


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DÉCLARATION DE CONFORMITÉ



ACEM

ACEM SpA

Via della tecnica, 29
40050 Argelato (Bologna) – Italy

S.p.A.

Déclarons sous notre seule responsabilité que le produit,

Typologie: éclairages chirurgicaux

Nom: STARLED3 NX , STARLED3 NX - satellite

Dans les versions: PLAFOND, MURAL, TROLLEY, TROLLEY ABPS

sont conforme a les prescriptions de la **Directive Dispositifs Médicaux 93/42/EEC;**

Sont classés conformément à l'annexe IX - Règle 1, tels que,

Classification: I

Et sont conformes aux normes harmonisées:

EN-60601-1:2007-05 et Variante EN 60601-1/A1:2014-09

“Appareils électromédicaux

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles”.

EN-60601-2-41:2011-10 et Variante EN 60601-2-41/A1:2016-12

“Appareils électromédicaux

Partie 2: Exigences particulières pour la sécurité de base et les performances essentielles des éclairages chirurgicaux et des éclairages de diagnostic”.

et est compatible avec la Directive :

2015/863/CE RoHS3

“Restriction de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques”.

Lieu et date:

Stampe et signature Direction Générale

Argelato, 15 Janvier 2018


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SURGICAL LED LAMP

STARLED3 NX



STARLED3 NX

IS A LAMP MANUFACTURED BY ACEM MEDICAL COMPANY BASED ON THE NEXT GENERATION LED TECHNOLOGY, ASSURING COLD LIGHT, LONG LIFE AND LOW ENERGY CONSUMPTION. THE LAMP IS SUITABLE FOR COUNTLESS APPLICATIONS BOTH FOR SURGERY AND OPERATING ROOM. IT IS IDEAL FOR DIAGNOSIS, DENTAL SECTOR, GYNAECOLOGY, DERMATOLOGY, GENERAL MEDICINE AND SURGERY.

STARLED3 NX grants a homogeneous and shadowless light focusable according to needs. The visual area is perfectly illuminated assuring both excellent lighting comfort and working conditions.

The Lamp provides:

- **HIGH LIGHT INTENSITY**
- **IR-FREE LIGHT**
- **VARIABLE COLOUR TEMPERATURE (TW VERSION)**
- **EXCELLENT COLOR RENDERING INDEX (CRI)**
- **FOCUSABLE LIGHT BEAM**
- **LONG LIFE**
- **LOW ENERGY CONSUMPTION**



STARLED3 NX is composed by three reflectors that produce a well-blended and intense cone of light focusable through the specific function on the control panel.

The design is slim, practical, compact and functional. The lamp is ergonomic, easy to move and to position and suitable for the laminar flows of the operating room.

Thanks to its ENDO function (light for endoscopy) **STARLED3 NX** is also suitable for minimal-invasive surgery.

The easy to clean shape and material of **STARLED3 NX** as well as its removable, sterilizable and easy to grip handle assure an excellent cleanliness.



Functions are adjusted by the innovative easy to read, ergonomic and easy to clean I-SENSE control panel. With a simple touch it can manage easily and accurately:

- ON/OFF Function
- Light intensity adjustment
- DoF - Depth of Field - for a deep light
- ENDO - Light for endoscopy ideal for minimal-invasive surgery
- SIZE - Light spot diameter adjustment to focus the operating area
- SYNC – (optional) Function to synchronize controls of combined lamps: **STARLED3 NX** double (twin dome configuration) and **STARLED3 NX** together with **STARLED5 NX**

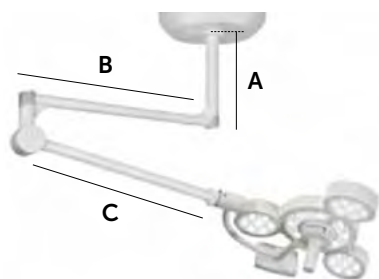


TECHNICAL DATA SHEET

Protection class (EN 60601-2-41)	I
Power Supply	100 - 240 VAC $\pm$ 10%
Power consumption	69 W
Frequency	50/60 Hz
Light source	LED
Average life	60,000 HOURS ABOUT
Lighting at the centre, Ec @ 100 cm	130,000 LUX 160,000 LUX (OPTIONAL)
Light adjustment	FROM 5 % TO 100%
Colour temperature, CCT (STANDARD)	4,500 K
Variable colour temperature (TW VERSION)	FROM 3,700 K TO 4,700 K continuous

Colour rendering index, Ra	95
Index R9	> 90
Light field diameter	24 - 33 cm
Focusable working distance	70 - 150 cm
Lighting depth L1+L2 (20%)	117 cm
Lighting depth L1+L2 (60%)	71 cm
Light head weight	4 Kg
Light head diameter	50 cm
Handle	REMOVABLE AND STERILIZABLE
Colour	WHITE RAL 9002

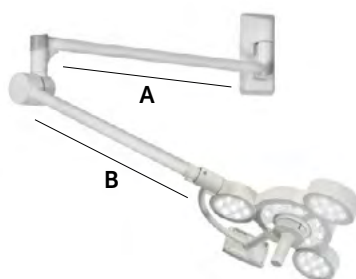
STARLED3 NX IS AVAILABLE IN THE FOLLOWING CONFIGURATIONS



A = FROM 250 mm TO 1,100 mm
B = 800 mm C = 720 mm

CEILING MOUNTED
(single, double - twin dome - or in
combination with STARLED5 NX)

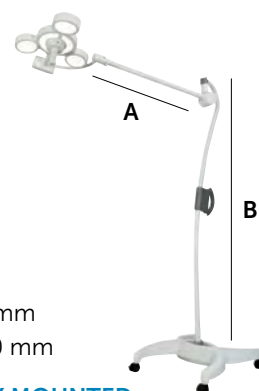
Weight of support 6.0 - 9.0 Kg



A = 800 mm
B = 720 mm

WALL MOUNTED

Weight of support 5.3 Kg



A = 550 mm
B = 1.750 mm

TROLLEY MOUNTED
(Battery on demand)

Weight of support 23 Kg

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ACEM RESERVES THE RIGHT TO MODIFY THE DESIGN AND SPECIFICATIONS
CONTAINED HEREIN WITHOUT ANY PRIOR NOTICE.

DEP.STARLED3NX.OPT.TW.EN R2101



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