

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.


ACEM SpA
VIA DELLA TECNICA 29
40050 ARGELATO (BO) ITALY
TEL. +39 051/721844 FAX. +39 051/721855
PWA 01647771201

	TECHNICAL DOCUMENTATION EU DECLARATION OF CONFORMITY	Rev.	r2101
		Code	EU DOC_SLED3 NX
	Surgical Lamp STARLED3 NX	Date	26/04/2021
		Page 1 / 2	

REVISION HISTORY		
Rev.	Date	Description
r2101	26/04/2021	First issue

Drawn up by	Verified by	Approved by
LP	GS	PPT
Luca Petrolo	Giuseppe Serafini	Pier Paolo Tacconi
SIGNATURE 	SIGNATURE 	SIGNATURE  <small>ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABDELATO (BO) ITALY TEL. +39 051/721844 FAX. +39 051/721855 P.IVA 01647771201</small>

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EU DECLARATION OF CONFORMITY


Name of the manufacturer	ACEM S.p.a.
Registered place of business	Via della Tecnica 29 40050 Argelato (BO) - Italia
Contact details	+39 051 721844 info@acem.it
Manufacturer's unique registration number (SRN)	Pending

This declaration of conformity is issued under the sole responsibility of the manufacturer and states that the device

Type	Surgical Lamp
Brand	STARLED3 NX
Models	Code
STARLED3 NX/W	110602
STARLED3 NX/T	110603
STARLED3 NX/TB	110604
STARLED3 NX/SC1	110605
STARLED3 NX/SC2	110606
STARLED3 NX/MC1	110607
STARLED3 NX/MC2	110608
STARLED3 NX/CC2	110610
STARLED3 NX/CC3	110611
Basic UDI-DI	805070589STARLED3NXM6
Intended Use	Single luminaire in the PATIENT ENVIRONMENT which is intended to support treatment and diagnosis which can be interrupted without any HAZARD for the PATIENT in case of failure of the light and to be used in operating rooms.
Risk Class	Class I according to Annex VIII Regulation (EU) 2017/745

meets the requirements of Regulation (EU) 2017/745

All documentation supporting this declaration is filed with the manufacturer.

Place and date	Argelato, 26/04/2021
Name and surname	Pier Paolo Tacconi
Role	CEO
Signature	 ACEM S.p.A. VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051/721844 FAX. +39 051/721855 P.IVA 01647771201

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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Mutual Recognition Agreements

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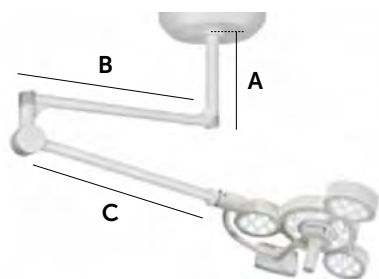
 **TÜVRheinland®**

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

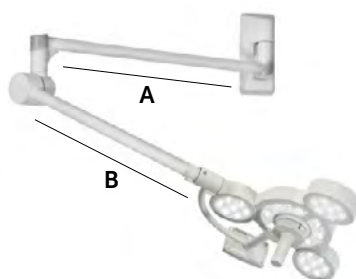
STARLED3 NX IS AVAILABLE IN THE FOLLOWING CONFIGURATIONS



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)

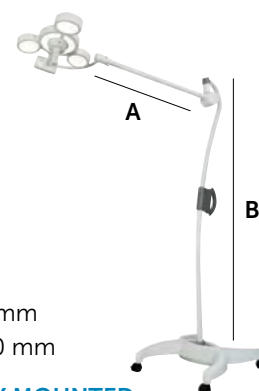
Weight of support 6.0 - 9.0 Kg



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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DEP.STARLED3NX.OPT.TW.EN R2101



ACEM SPA | VIA DELLA TECNICA 29, 40050 - ARGELATO, BOLOGNA - ITALY
PH +39 051 721844 | FAX +39 051 721855 | info@acem.it | **WWW.ACEM.IT**



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EN ISO 13485:2016
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9. STARLED3 NX TECHNICAL DATA SHEET

9.1 Electrical features

Voltage at SMPSU	100-240 VAC $\pm 10\%$ - 50/60 Hz
Max power consumption	69 W (87 @ 160.000 lux)
Light head power supply	24 VDC
Class (EN 60601-2-41)	I

9.2 Light source technical data

Light source:	LED
Average life:	50,000 hours
Max illuminance at centre, Ec	130,000 lux, (160.000 lux option)
Light adjustment range	5% ~ 100%
Colour temperature, CCT	4,500 °K
Chromatic coordinates	x=0.365, y=0.370 +/- 1%
Colour rendering index, R _A	95
Colour rendering index, R ₉	92
Light field dimension d ₁₀	24 - 33 cm
Light field dimension d ₅₀	13 - 17 cm
Focusable working distance	70 - 150 cm
Remaining lighting as to Ec narrow field (width)	
with one mask	58 % (48 %)
with two masks	49 % (46 %)
with standardized cylinder	99 % (99 %)
with standardized cylinder and one mask	61 % (50 %)
with standardized cylinder and two masks	55 % (51 %)
Lighting depth L1+L2:	117 cm (@ 20%), 71 cm (@ 60%)
Irradiance @ max illuminance:	
Visible	377 W/m ² (130K lux) - 465 W/ m ² (160K lux)
IR	0.02 W/m ²
UV	0.02 W/m ²
Irradiance/illuminance	2.90 mW/m ² /lux
Photometric radiation equivalent	344 lm/W

Data taken according to Standard EN 60601-2-41:2009.

Note: all photometric values are subject to 5% tolerance.

9.3 Weight, dimensions and additional information

Light head weight	4.2 kg
Light head Diameter	50 cm
Colours	RAL 9002
Max light head temperature	45°C max
IP degrees	IP40