

	TECHNICAL DOCUMENTATION EU DECLARATION OF CONFORMITY	Rev.	r2201	
		Code	EU DOC_STARLED3 NX	
	Surgical Lamp STARLED3 NX		Date	30/03/2022
				Page 1 / 2

REVISION HISTORY		
Rev.	Date	Description
r2101	26/04/2021	First issue
r2201	30/03/2022	DT Revision

Drawn up by	Verified by	Approved by
RQ	PRRC	DG
Giuseppe Serafini	Pier Paolo Tacconi	Pier Paolo Tacconi
SIGNATURE	SIGNATURE	SIGNATURE
	 <small>ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABBELATO (BO) ITALY TEL. +39 0517721844 FAX. + 39 051/721855 P.IVA 01647771201</small>	 <small>ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABBELATO (BO) ITALY TEL. +39 0517721844 FAX. + 39 051/721855 P.IVA 01647771201</small>

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				Page 2 / 2

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)	IT-MF-000022748

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, 30/03/2022
Name and surname	Pier Paolo Tacconi
Role	CEO
Signature	 <small>ACEM SPA VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051 721844 FAX. + 39 051/721855 PWA 01647771201</small>