

	<b>TECHNICAL DOCUMENTATION</b> <b>EU DECLARATION OF CONFORMITY</b>	Rev.	r2101
		Code	EU DOC_SLED5 NX
	Surgical Lamp <b>STARLED5 NX</b>	Date	26/04/2021
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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 

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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 <a href="mailto:info@acem.it">info@acem.it</a>
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	STARLED5 NX
Models	Code
STARLED5 NX /T	110703
STARLED5 NX /MC1	110707
STARLED5 NX /MC2	110708
STARLED5 NX /CC2	110710
STARLED5 NX /CC3	110711
STARLED5 NX /DC1	110713
STARLED5 NX /DC2	110714
STARLED5 NX /DC3	110715
Basic UDI-DI	805070589STARLED5NXMG
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	<b>Class I</b> 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 SPA VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051 721844 FAX. +39 051 721855 P.IVA 01647771201