

	TECHNICAL DOCUMENTATION EU DECLARATION OF CONFORMITY	Rev.	r2201
		Code	EU DOC_STARLED5 NX
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REVISION HISTORY		
Rev.	Date	Description
r2101	26/04/2021	First issue
r2102	10/06/2021	Added conformity with RoHS3
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  ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABBELATO (BO) ITALY TEL. +39 0517721844 FAX. + 39 051/721855 P.IVA 01647771201	SIGNATURE  ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABBELATO (BO) ITALY TEL. +39 0517721844 FAX. + 39 051/721855 P.IVA 01647771201

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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)	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	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 lamp or lamp system, used in the PATIENT AREA, intended for the purpose of facilitating treatment and diagnosis and for use in operating theaters.
Risk Class	Class I according to Annex VIII Regulation (EU) 2017/745

meets the requirements of Regulation (EU) 2017/745
and comply with Directive 2015/863/CE RoHS3

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	 ACEM SPA VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051721844 / FAX. + 39 051/721855 P.IVA 01647771201