
	TECHNICAL DOCUMENTATION EU DECLARATION OF CONFORMITY	Rev.	r2201
		Code	EU DOC_ACEMSO15
	Luminaire for diagnosis SOLED15, SOLED15-F, ACEMSO15F	Date	30/03/2022
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REVISION HISTORY		
Rev.	Date	Description
r2101	26/04/2021	First issue
r2201	30/03/2022	Revision

Drawn up by	Verified by	Approved by
RQ	PRRC	DG
Giuseppe Serafini	Pier Paolo Tacconi	Pier Paolo Tacconi
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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	Luminaire for diagnosis
Brand	SOLED15, SOLED15F, ACEMSO15F
Models	Code
SOLED15 /W	110302
SOLED15 /T	110303
SOLED15 /TB	110304
SOLED15 /SC1	110305
SOLED15 /SC2	110306
SOLED15-F /W	110402
SOLED15-F /T	110403
SOLED15-F /TB	110404
SOLED15-F /SC1	110405
SOLED15-F /SC2	110406
ACEMSO15F /W	110502
ACEMSO15F /T	110503
ACEMSO15F /TB	110504
ACEMSO15F /SC1	110505
ACEMSO15F /SC2	110506
Basic UDI-DI	805070589ACEMSO15QH
Intended Use	Luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light. NOTE It is not intended 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 S.p.A. VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051 721844 FAX. +39 051 721855 P.IVA 01647771201</small>