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MODIFICATION NOTES		
Rev	Date	Description
r2001	01/07/2020	First issue
r2201	30/03/2022	Dt Revision

Written by	Verified by	Approved by
RQ	PRRC	DG
Giuseppe Serafini	Pier Paolo Tacconi	Pier Paolo Tacconi
SIGNATURE 	SIGNATURE  <small> ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABELATO (BO) ITALY TEL. +39 051/721844 FAX. + 39 051/721855 P.IVA 01647771201 </small>	SIGNATURE  <small> ACEM S.p.A. VIA DELLA TECNICA 29 40050 ABELATO (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.
Address of the manufacturer	Via della Tecnica 29
Contacts	+39 051 721844 info@acem.it
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	ACEMST1		
Models	Code	Models	Code
ACEMST1.1 /RR	110800	ACEMST1.1 /FR	110900
ACEMST1.1 /RD	110801	ACEMST1.1 /FD	110901
ACEMST1.1 /RW	110802	ACEMST1.1 /FW	110902
ACEMST1.1 /RT	110803	ACEMST1.1 /FT	110903
ACEMST1.1 /RTB	110804	ACEMST1.1 /FTB	110904
ACEMST1.1 /RC	110805	ACEMST1.3 /FR	111100
ACEMST1.3 /RR	111000	ACEMST1.3 /FD	111101
ACEMST1.3 /RD	111001	ACEMST1.3 /FW	111102
ACEMST1.3 /RW	111002	ACEMST1.3 /FT	111103
ACEMST1.3 /RT	111003	ACEMST1.3 /FTB	111104
ACEMST1.3 /RTB	111004		
ACEMST1.3 /RC	111005		
Basic UDI-DI identifier of the device	805070589ACEMST1EM		
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	 ACES S.p.A. VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051/721844 FAX. +39 051/721855 P.IVA 01647771201