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|  | TECHNICAL DOCUMENTATION EU DECLARATION OF CONFORMITY | Rev. | r2201 |
| | | Code | EU DOC_STARLED5 NX |
| | Surgical Lamp STARLED5 NX | Date | 30/03/2022 |
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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  <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


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| 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

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| 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.

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| Place and date | Argelato, 30/03/2022 |
| Name and surname | Pier Paolo Tacconi |
| Role | CEO |
| Signature |  ACEM S.p.A. VIA DELLA TECNICA 29 40050 ARGELATO (BO) ITALY TEL. +39 051/721844 FAX. +39 051/721855 P.IVA 01647771201 |