



# DECLARATION OF CONFORMITY

# ACEM

**ACEM SpA**

Via della tecnica, 29  
40050 Argelato (Bologna) – Italia

S.p.A.

Declare under its sole responsibility, that the product,

**Type: Minor Surgical Luminaire**

**Name: STARLED3 NX , STARLED3 NX - satellite**

**Versions: CEILING, WALL, TROLLEY, TROLLEY ABPS**

comply with the requirements of the **Medical Devices Directive 93/42/EEC**;  
are classified according annex IX - rule 1, as,

**Class: I**

and comply with harmonized standards:

**EN-60601-1:2007-05 and Variant EN 60601-1/A1:2014-09**

“Medical electrical equipment.

Part 1: General requirements for basic safety and essential performance”.

**EN-60601-2-41:2011-10 and Variant EN 60601-2-41/A1:2016-12**

“Medical electrical equipment.

Part 2: Particular requirements for basic safety and essential performance of surgical luminaires  
and luminaires for diagnosis”.

and with Directive:

**2015/863/CE RoHS3**

“Restriction of the use of certain hazardous substances in electrical and electronic equipment”.

Place and Date:

Stamp and general manager signature

Argelato, 15th January 2018.

  
ACEM SpA  
VIA DELLA TECNICA 29  
40050 ARGELATO (BO) ITALY  
TEL. +39 051/721844 FAX. +39 051/721855  
PWA 01647771201