

ACEN

ACEM SpA

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

Declare under its sole responsibility, that the product,

Type: Minor Surgical Luminaire

Name: STARLED3 NX , STARLED3 NX - satellite Versions: CEILING, WALL, TROLLEY, TROLLEY ABPS

complies 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.

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