

CE 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
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