

Notified Body n° 0426



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CERTIFICATE N° 254-01-00-DM

(in compliance with Annex II of the Directive 93/42/EEC)

ITALCERT

certifies that the

Full Quality Assurance System
applied for the design, manufacture and final inspection
of "Medical Devices" - MD -

by the manufacturer

CASALUCI S.r.l.

S.S. 16 MAGLIE-LECCE KM. 978 SN
73022 CORIGLIANO D'OTRANTO (LE) - ITALY

in the headquarters located in

S.S. 16 MAGLIE-LECCE KM. 978 SN
73022 CORIGLIANO D'OTRANTO (LE) - ITALY

complies with the requirements stated in

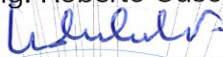
Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the same manufacturer to mark



in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito


MANAGING DIRECTOR

First issue date
2014-07-09

Renewal date
2019-08-27

Expire date
2024-05-26

This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n°254-01-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

Annex 1 to Certificate n° 254-01-00-DM

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Active medical device intended to administer and/or remove medicines, body liquids or other substances to or from the body in a potentially hazardous manner (class IIb)

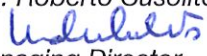
WALL - BED HEAD SYSTEM – *prepared for the insertion of components of medical gases and vacuum pipeline systems and anaesthetic gases scavenging systems*

- TOTEM
(models: HYDRA-P, SPAZIO-P)
- THE NEXTSYSTEM
(models NXT100-P, NXT200-P, NXT300-P, NXT400-P, NXT500-P, NXT600-P)

WALL - BED HEAD SYSTEM – *provided with components of medical gases and vacuum pipeline systems and anaesthetic gases scavenging systems*

- TOTEM
(models: HYDRA-G, SPAZIO-G)
- THE NEXTSYSTEM
(models NXT100-G, NXT200-G, NXT300-G, NXT400-G, NXT500-G, NXT600-G)

Milan, 2019-08-27

dr. ing. Roberto Cusolito

Managing Director