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CERTIFICATE

Certificate Number **UCN** : **801782470514**
Job : J21386
Date of Issue : 2017-05-16
Certificate valid up to : 2021-05-15

Brand Name : /
Type : Medical lights
Model N : KS-Series, MST-Series, SL-Series, LED-Series


Manufacturer : Shantou Easywell Technologies Co.,Ltd.
Address : 6th Floor H5 Building, No.16 Lianjiang Road,
Shantou, China

Standard Used : EN ISO 14971:2012, EN 1041:2008, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-2-41:2009

Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity	✓ OK
Test report reference : 17ZCTS0418004LR/17ZCTS0418379LR/17ZCTS0418379LR/17ZCTS0418379LR	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

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Massimiliano Bertoldi
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