## CELAB®

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## CERTIFICATE

Certificate Number UCN : 8021035 54057

Job : J24278

Date of Issue : 2018-07-06

Certificate valid up to : 2022-07-05

Brand Name : KUANGS

Type : Weighted Blanket Model N : Weighted Blanket

Manufacturer : Hangzhou Kuangs Textile Co., Ltd

Address : Hong quan Road, Yipeng, Xiaoshan, Hangzhou,

Zhejiang, China

Standard Us ed : EN ISO 13485: 2016+AC:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008,

EN ISO 10993-1:2009+AC:2010

## 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	V OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference; MOS1806263678S	V OK
Presence of C  symbol in the product label.	₽ OK
Presence of instruction manual	V OK
Use of valid Harmonized standard in the declaration of conformity	V OK
Presence of product description in the technical construction file	V OK

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Massimiliano Bertoldi General Manager – CELAB

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