

CE Documentation Review



No. 0L180914.HKMTC10

Holder: HeBei KangJi Medical Instrument Co., Ltd.

South Side, West Section of Chang'an Road
Feixiang Town, Feixiang District, Handan City,
Hebei Province

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Absorbent Cotton Sliver, Absorbent Cotton Ball, Absorbent Cotton Roll, Cotton Swab, Gauze Bandage, Gauze Block, Double Head Cotton Swab, Disposable Mask

(see the following annex I)

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. CE/MDD-KJ-2018. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 14 September 2018

Expiry date 13 September 2023

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Annex I

No. 0L180914.HKMTTC10

Product Name	Type
Absorbent Cotton Sliver	1g/m, 1.5g/m, 2g/m, 3g/m, 4g/m, 5g/m, 6g/m, 7g/m, 8g/m, 9g/m, 10g/m, 12g/m, 15g/m, 20g/m.
Absorbent Cotton Ball	Large(0.8g~1.0g/grain), Medium(0.5g~0.7g/grain), Small(0.1g~0.4g/grain).
Absorbent Cotton Roll	1000g, 500g, 450g, 400g, 350g, 300g, 250g, 100g, 50g, 10g, 5g.
Cotton Swab	7cm, 8cm, 10cm, 12cm, 15cm, 20cm; 1 piece/bag, 2 pieces/bag, 4 pieces/bag, 5 pieces/bag, 6 pieces/bag, 8 pieces/bag, 10 pieces/bag, 15 pieces/bag, 20 pieces/bag, 25 pieces/bag, 30 pieces/bag, 40 pieces/bag, 45 pieces/bag, 50 pieces/bag, 70 pieces/bag, 80 pieces/bag, 90 pieces/bag, 100 pieces/bag.
Gauze Bandage	Classified by length: 200cm, 300cm, 350cm, 400cm, 450cm, 500cm, 600cm, 800cm, 1000cm, 1200cm according to the length. Classified by width: 4cm, 4.8cm, 6cm, 8cm, 10cm, 12cm, 15cm. Classified by the minimum number of packages: 1 piece, 2 pieces, 3 pieces, 4 pieces, 5 pieces, 8 pieces, 10 pieces.
Gauze Block	Length: 50mm, 60mm, 70mm, 80mm, 100mm, 120mm, 140mm, 150mm, 200mm; Width: 40mm, 50mm, 60mm, 70mm, 80mm, 100mm, 120mm, 140mm, 150mm. The number of folded layers is 8 layers.
Double Head Cotton Swab	7.5cm*100, 7.5cm*150, 7.5cm*200, 7.5cm*300, 7.5cm*350, 7.5cm*500.
Disposable Mask	17cm*8cm, 17cm*9cm, 17cm*9.5cm, 17cm*10cm, 17.5cm*8cm, 17.5cm*9cm, 17.5cm*9.5cm, 17.5cm*10cm, 18cm*8cm, 18cm*9cm, 18cm*9.5cm, 18cm*10cm, 19.5cm*8cm, 19.5cm*9cm, 19.5cm*9.5cm, 19.5cm*10cm.

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