

CE Documentation Review



No. 0I200330R.JHG0D03

Holder: JIANGSU HUBAO GROUP CO.,LTD
HuaYang Road, ChaHe Town, Hanjiang District,
Yangzhou, Jiangsu, China

Review goal: Verification of the presence of Technical
Documentation compatible with the Medical
Devices Directive 93/42/EEC Annex VII

Product: Disposable isolation clothing (Not Sterile)

Model(s): 160, 165, 170, 175, 180, 185(size)

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's
declaration)

Review output: This document has been issued on a voluntary
basis and upon request of the manufacturer. It is
our opinion that the Technical Documentation
shared with us by the manufacturer is
compatible with the European Standard for
Medical Devices.
The manufacturer is responsible for the CE
Marking process, and not exempted to carry
out all necessary compliance activities. This
document has been issued on the basis of the
regulation on ECM Voluntary Mark for the
certification of products. RG01_ECM rev.3
available at: www.entecerma.it

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