

CE Documentation Review



No. 0B200319.ZUDPUS84

Holder: Zhejiang Ugly Duck Industry Co., Ltd.
No. 2 Dongfang South Road, Ouhai District, Wenzhou
City, Zhejiang Province, China

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

Product: Medical protective clothing (**no sterile**)
Model(s): 2020313

Classification: Class I (no sterile)
(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.
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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Expiry date: 18 March 2025

Reviewer
Technical expert
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