



# CE Documentation Review

No. OP200317.FLPUC73

**Holder:** Pharmaceutick Pharmaceutical Industry Co., Ltd.  
Longyan economic and technological development zone, province

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

**Product:** Single-use protective clothing for medical use (**no sterile**)

**Model(s):** Overall, Split type

**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. Technical File identified with the no. **TMDDMJ2003123551-AG02-75**.  
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](http://www.entecerma.it)

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**Expiry date:** 16 March 2025

Reviewer  
Technical expert  
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