

CE Documentation Review



No. OP200317.ZLMUQ98

Holder: Zhejiang Lanhine Medical Products
1989 Cidong Road, Cidongbinhai District, 315300
Cixi City, Zhejiang Province, People's Republic of
China

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

Product: Face shield (**no sterile**)
Model(s): adjustable type; spectacle frame type;
head cover sponge type; ear hanging
sponge 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-AG02-12.
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: 16 March 2025

Reviewer
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