

# CE Documentation Review



No. [REDACTED]

Holder: [REDACTED]

Manufacturer: [REDACTED]

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 medical face mask/surgical mask (no sterile)

Model(s):

☐ Flat hanging ears

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. 202CTS0309001LR. 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 12 March 2020

Expiry date 11 March 2025

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