

# CE Documentation Review



No. 0P200316.SSMUQ28

Holder: Shenyang Shengshi Medical Technology Co., LTD.

No.12-2 Kunming Lake Street, Shenyang Economic and Technological Development Zone, Shenyang City, Liaoning 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: N95 medical protective mask (no sterile)  
Model(s): 14cm\*9cm, 14.2cm\*9cm, 14.4cm\*9cm, 14.6\*9cm, 14.8cm\*9cm, 15cm\*10cm, 15.2cm\*10cm, 15.4cm\*10cm, 15.6cm\*10cm, 15.8cm\*10cm, 16cm\*11cm, 16.2cm\*11cm, 16.3cm\*11cm, 16.4cm\*11cm, 16.5cm\*11cm

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. **TMLN20031222296**.

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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Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni

**Ente Certificazione Macchine**

Via Ca Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy  
☎ +39.0516705141 📠 +39.0516705156 ✉ [info@entecerma.it](mailto:info@entecerma.it) 🌐 [www.entecerma.it](http://www.entecerma.it)