

# CE Documentation Review



No. 2S200411.TESTT90

Holder:

**TTAF ELEKTRONİK SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Kavaklı Mah. İstanbul Cad. No:21 Beylikdüzü / İstanbul / TURKEY

Review goal:

Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product:

Face Shield (Not Sterile)

Model(s):

T-PET, T-PET-G, T-PET-EU

Classification:

Class I (Not Sterile)  
(accordingly to the Manufacturer's declaration)

Review output:

This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. 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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Approver

ECM Service Director

Luca Bedonni



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Technical Expert

Amanda Pavia



**Ente Certificazione Macchine**

Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy

+39.0516705141 +39.0516705156 info@entecerma.it www.entecerma.it