

CE Documentation Review



No. 0H200329S.DTP0W43

Holder: Dongguan Tianwei Precise Silicone Products Co., Ltd

No.1,Dapu Industrial Zone, Muling Street, Gangzi Village, Changping Town, Dongguan City, Guangdong province, China

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

Product: Reused Silicone Face Mask (Not Sterile)

Model(s): 13*10*8cm, 11*8.5*7cm

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. Technical documentation identified with the no. XMT0202001227LY/MDD dated 29 March 2020. 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

Date of issue 29 March 2020

Approver
ECM Service Director
Luca Redonni



Expiry date 28 March 2025

Technical Expert
Amanda Payne

