

CE Documentation Review



No. 4M200324T.GDO0D73

Holder: GUANGDONG DONGHUA
OPTOELECTRONICS TECHNOLOGY
CO., LTD.

Kengkou Ind Zone, Dean Village, Houjie Town,
523943, Dongguan, Guangdong, China

Manufacturer: GUANGDONG DONGHUA
OPTOELECTRONICS TECHNOLOGY
CO., LTD.

Kengkou Ind Zone, Dean Village, Houjie Town,
523943, Dongguan, Guangdong, China

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

Product: Face Mask (Not Sterile)

Model(s): DH-511

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.
20ZCTS0313014SP.

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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