## **C** € Documentation Review

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No. 5C200401R.ZBS0T04

Holder: Zhejiang Bada Sport Inc

#88 TaiDa Street, Qian Xi Town,

Wucheng District, Junhua, Zhejiang, China

Review goal: Verification of the presence of Technical

Documentation compatible with the Medical

Devices Directive 93/42/EEC Annex VII

Product: Disposable Surgical Mask (Not Sterile)

Model(s): BD2020

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.

20ZCTS0330031SP

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 01 April 2020 Approver ECM Service Director Luca Bedonni Expiry date 31 March 2025

Technical Expert
Amand