



EU DECLARATION OF CONFORMITY

Distributed by: JBM CAMPLLONG, S.L.U.

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CIF: ESB17419292

Product's description: ANTI-FOG PROTECTION MASK

Manufacturer's reference: 300677

Distributor's reference: 53798

The declaration object complies with the Directives 93/42/EEC and 2007/47/EEC; and the following standards:

Standard	Title	Edition/Date
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN 1041	Information supplied by the manufacturer of medical devices	2013
EN ISO 10993-1	Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical devices	2010
EN ISO 10993-5	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2013

Signed by:



Eduard Godoy

Purchasing department director

Girona, 18th August, 2021



EC Declaration of Conformity
Regarding Medical Device Directive (93/42/EEC)
Including Directive 2007/47/EEC

Applicant

Product

Name: Face shield

Item no: 300677

Classification: Class I

Rule: According to rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO10993-1:2010
EN ISO10993-5:2009
EN ISO10993-10:2013



Signature:

Date: March 26, 2020