

QA Documentation check used in Opportunities

A documentation check is used to establish if the product on offer is manufactured with a recognised QMS and the product offered conforms to the Standards required of it.

And if those manufacturers are outside the EU, that the documentation has evidence of a connection with a recognised notifiable body.

The process used is as follows:

Review documentation for evidence that the supplier/manufacturer/ distributor/third party provider has the following. This come in many forms.

Certificate of QMS

Certification should show the Manufacturer has accreditation to a recognised Quality management system that supports the manufacturing of the Product on offer.

Evidence within the certificate that it is in line with Medical device directive 93/42/EEC. Evidence of the Classification of the medical device should also be evident

And relevant standards i.e PPE standards

If the manufacturer is outside the EU and states it is CE marked it must have evidence of an European Authorised representative. (I.e. notified body) within the document.


Masks Certs.pdf

Examples



ZERTIFIKAT • CERTIFICATE • 证书 • CERTIFICADO • CERTIFICAT

EC Certificate
Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in astatic conditions, sterilised systems or procedure packs)
No. G2S 17 02 62151 011

Manufacturer: Sino Protection (Hefei) Medical Products Co., Ltd.
Area 3, Kazuo Industrial Park
Xingjun Road
230011 Hefei
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Erfordia 40
20357 Hamburg
GERMANY

Product Category(ies): Surgical Gown, Surgical Drape, Surgical Pack, Coverall, Non-woven Swabs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective device / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH17364EXT01

Valid from: **I&S**

Valid until: **PD**

Date: 2017-03-09

TÜV SÜD Product Service GmbH is Notified Body with certification no. 0123.
Page 1 of 2

TÜV SÜD Product Service GmbH • Zertifikatsstelle • Rüdigerstraße 35 • 80339 München • Germany

Certificate of compliance / conformity

This document should relate to the product that is being manufactured using the accredited QMS certificate, it provide evidence that provide has been manufactured and tested to the relevant technical standards example.

ISET S.r.l. Unipersonale
Sede Legale e Uffici
Via Donatello di Seregno, 9 - 48024 Mugello (MO)
Tel. e fax +39 (0)576 500983
www.iset-italia.eu - info@iset-italia.com

Cap. soc. i.a. € 10.000,00
Cod. Fisc. e P.IVA Reg. Imprese 02 332 750 369
REA
Cap. soc. i.a. MN 0221096

CERTIFICATE
Certificat - Certificado- Сертификат - Zertifikat - 證書

1) **APPLICANT:** ()
[Redacted] Science and Technology [Redacted] ad,
Xia [Redacted]

MANUFACTURER:
Shenzhen DJ Medical Equipment Co. Ltd.
B [Redacted] Fir [Redacted] road,
Xiaomang [Redacted] d. L. [Redacted] coma

2) **CERTIFICATE NO.:** I/SETC 000220200135
FILE REFERENCE: ENC2003041GZ30E1

3) **ISET MARK:**

4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):
 The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

5) **TYPE OF PRODUCT:** Medical isolation eyes cover
MODEL(S): GLYZ1-1, GLYZ1-2, GLYZ1-3

6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Personal Protective Equipment 2016/425, EN 166:2001

7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.

8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

9) **DATE OF ISSUE:** 13/03/2020 **EXPIRY DATE:** 12/03/2025

10) **SIGNATURE:** Miriam Camplone
(On behalf of the Legal representative)

PD



This document is property of ISET Srl and any kind of reproduction is to be considered strictly forbidden.

And if the certificate refers to a standard that has a performance level designated in it, the certificate should make it clear at what performance level the product being made to. Example



Declaration of
Conformity Type II F

If not, a supporting set of test data that refers the product line in question needs to be provided



Technical
Documentation of S
Example

If a Marketing leaflet is provided, reject and request the above

To Query and ask for Clarification on documentation

Documentation review certificates are certificates that Shows the manufacturer has had their QMS



checked (Does not prove anything on the validity of the product) example
93_42_EEC
DIRECTIVE copy Type

These can probably be used as evidence of QMS system accreditation but need to be supported with the appropriate Certificate on compliance/conformity.

Documentation not in English. If the above documents do not align, using the test data may bring clarity. But if in Chinese, they need to be rejected.

Harmonisation of standards.

Opportunities that quote US / Chinese standards will require clarification that these standards are acceptable.

I.e. Respiratory protection equipment standards.

.