 Asesoría de Consumo y Sanidad	NIF: B91985978 C/ Ramiro Monje s/n, edif. 12, 3ºA 11310 San Roque, Cádiz	
	Nº: 30032020BF	Página 1 de 2
CERTIFICATE	December 2019	VERSION Nº 2

Manufacturer: WENZHOU BADA OPTICAL CO LTD

Address: 88 Jingyu Roal Louqiao, Industrial Zone, Ouhai,, Wenzhou, 325000, China

Product: Medical protective Eyewear, Goggles and Face Shield BDGX-GLYZ Series

Standards: ISO 13485, ISO 14971:2012, ISO 15223-1:2012, EN 1014, ISO 10993-1, UNE EN 166:2001


Annex I: Declaration of conformity Directive 93/42

Conclusion:

After inspection of technical documentation issued by the customer and in his request, we express our opinion that the product meets the technical requirements of the following directives and standards: 93/42/EEC Medical Devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with all applicable legal requirements for the product.


The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : SCC(20)-60043S-MDD	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK



27th April 2020

Fdo digitalmente por Javier Velasco Ramírez
Gerente ASECONSA Asesoría de Consumo y Sanidad

To verify the legality of this certificate contact direcciontecnic@aseconsa.es

 Asesoría de Consumo y Sanidad	NIF: B91985978 C/ Ramiro Monje s/n, edif. 12, 3ºA 11310 San Roque, Cádiz	
	CERTIFICATE	Nº: 30032020BF
	December 2019	VERSION Nº 2

Annex I:

Certification: 01/BADA/2020	
 CE DECLARATION OF CONFORMITY	
PRODUCT MANUFACTURER: WENZHOU BADA OPTICAL CO LTD	
ADDRESS: 88 Jingyu Roal Louqiao, Industrial Zone, Ouhai,, Wenzhou, 325000, China	
PRODUCT	
Name: Medical protective Eyewear, Goggles and Face Shield BDGX-GLYZ Series	
Models:	
<ul style="list-style-type: none"> • BDGX-GLYZ-01 • BDGX-GLYZ-02 • BDGX-GLYZ-03 • BDGX-GLYZ-04 • BDGX-GLYZ-05 	<ul style="list-style-type: none"> • BDGX-GLYZ-06 • BDGX-GLYZ-07 • BDGX-GLYZ-08 • BDGX-GLYZ-09 • BDGX-GLYZ-10
<i>ECRI code: 15-697 (Security glass)</i>	
CONFORMS WITH THE REQUISITES OF THE DIRECTIVES	
EC Directive 93/42/CEE and Directiva2007/47/EC:	
Annex VII Directive 93/42/EEC medical devices.	
Classification (rule):	Class I (rule 1)
OTHER INFORMATION:	
<i>European Authorized Representative:</i> <i>Name: Fudlong SL</i> <i>Address: C/ Gramil 25-1, Poligono Store, 41008 Sevilla</i>	
STANDARDS:	
<ul style="list-style-type: none"> • Directive 93/42 / EEC and Directive 2007/47 / ECDE Medical Devices. • ISO13485-Quality Management Systems of Medical Devices. • ISO 14971:2012. Risk Management System Medical Devices. • ISO 15223-1:2012. Symbols used on labels, labeling and information to be provided in Medical Devices. • Norma EN 1041. Information provided by the manufacturer of Medical Devices. • ISO 10993-1. Biological evaluation of Medical Devices. • MEDDEV 2.7.1. rev.3, December 2009 : Evaluation of clinical data : A guide for the manufacturers and notified body. • FDA – Parte 820 – Foods and Drugs Administration – Parte 820. • UNE EN 166:2001. Eye and face protectors. General requirements 	
30/03/2020	
DATE	GENERAL MANAGER