

## EC Declaration of Conformity

Manufacturer:

**BESTSAFE GLOVE CO., LTD.**

We, the manufacturer, herewith declare that the products

### Medical examination glove, Disposable glove

Meet the provisions of Directive MDR2017/745/EEC ,EN455 which apply to them

The medical device has been assigned to class 1 according to Annex VII of the Directive MDR2017/745/EEC ,EN455.

It bears the mark



The product concerned has been manufactured under a quality management system according to Annex AII of Directive MDR2017/745/EEC ,EN455

Following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive MDR2017/745/EEC ,EN455

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company **BESTSAFE GLOVE CO., LTD.**

Address : 52/43 Watkodhin-Kaophai rd. T.Tubma

A.Muang Rayong, Rayong 21000

Thailand.

Rayong – Thailand. 21.10.2020  
Place, date  
EC Declaration of Conformity  
ECD-01,00(DOC no, Revision)

*Pignat.C*

Chief Executive Officer  
Legally binding signature, Function

**EU DECLARATION OF CONFORMITY**  
**PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425**

We, **BESTSAFE GLOVE CO., LTD** 52/43 Watkodhin-Kaophai Rd. T.Tubma, .Muang Rayong Rayong. THAILAND 21000, hereby declare the following Personal Protective Equipment (PPE)

**DISPOSABLE POWDER FREE NITRILE GLOVES, PPE MODEL: BG0001**



Notified Body responsible for certification and ongoing conformity:

**SATRA Technology Europe Ltd,**

**Bracetown Business Park,**

**Clonee, Dublin**

**D15 YN2P, Ireland; Notified Body Number: 2777**

Relevant Harmonized Standards/ Technical Specifications used to which conformity is declared Safety glove standards:

EN ISO 21420: 2020 : General requirements and test methods
EN ISO 374-1:2016+A1:2018: Terminology and performance requirements for chemical risks
EN ISO 374-2: 2019: Determination of resistance to penetration
EN ISO 374-4:2019: Determination of resistance to degradation by chemicals
EN ISO 374-5:2016: Terminology and performance requirements for micro-organisms risks
EN16523-1: 2015+A1: 2018: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact



Piyawat Chirasakulkarun-Managing Director

Dated : December 24, 2020

# EU Declaration of Conformity (DoC)

We

Company name: BESTSAFE GLOVE CO.,LTD  
Postal address: 52/43 Watkodhin-Koaphai rd. T.Tubma A.Muang, Rayong, Rayong. Thailand  
Postcode: 21000  
City: Rayong  
Telephone number: +66-062-3256558, +66-086-3173770, +66-081-4022099  
E-Mail address: Sales@bestsafe.co.th

declare that the DoC is issued under our sole responsibility and belongs to the following product:

Apparatus model/Product: Safety glove, Nitrile  
Type: Disposable glove  
Batch: Depend on lot and issue production date  
Serial number: Bestsafe glove nitrile

Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):

Identification of the apparatus



The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

EMC Directive 2014/30/EU  
PPE [EU2016/425]  
EN374  
TIS 1056-2556

The following harmonised standards and technical specifications have been applied:

Title, Date of standard/specification:  
GMP  
ISO 13485  
ISO 9001  
ISO 14001  
...  
...

Notified body (where applicable): SATRA  
4 digit notified body number: 2777  
2777

Additional information:  
SATRA

Signed for and on behalf of: BESTSAFE GLOVES CO.,LTD  
2020-12-24

Place of issue  
Date of issue  
Name, function, signature

*Piyawat Chirasakulkarun*  
PIYAWAT CHIRASAKULKARUN  
 BESTSAFE GLOVE CO.,LTD

# SPECIFICATION

Product Specification			
Brand	N/A		
Product	Nitrile Examination Glove, Powder Free		
	Non sterile, Disposable		
Powder Content	Maximum 2.0 mg per Glove		
Protein Content	N/A		
Size (mm)	ISI 85±5, IW 95±5, QJ 106±5, QXL -min 110		
Avg Width (mm)	100 ± 10		
Avg Weight (g)	3.8 ± 0.3		
Length (mm)	Min 240 (9")		
Thickness	Cuff	0.08 ± 0.02	
	Palm	0.09 ± 0.02	
	Finger	0.11 ± 0.02	
Physical Properties - ASTM			
Parameters	Tensile (MPa)	Elongation Break (%)	Modulus 500% (MPa)
Before Aging			
Result	18	650 - 670	Max 28
ASTM Requirement	Min 14	Min 650	Max 28
After Aging			
Result	16	500 - 650	Max 28
ASTM Requirement	Min 14	Min 500	N/A
Physical Properties - EN			
Parameters	Force Break (N)	Elongation Break (%)	
Before Aging			
Result	6 - 10	N/A	
ASTM Requirement	Min 6	N/A	
After Aging			
Result		N/A	
ASTM Requirement		N/A	
Performance			
Inspection	Related Defects	Inspection Level	AQL
Watertight Test	Holes	G-1	1.5
Visual Inspection	Major Defects		2.5
	Minor Defects		4.0
Physical Properties	Tensile	S-2	4.0
Physical Dimension	Measurement	S-2	4.0
Features			
<ul style="list-style-type: none"> <li>Fingertp Textured</li> <li>Powder Free</li> <li>No Natural Latex</li> <li>Lab Chemical Tested</li> <li>Amidextrous</li> <li>Blue, White, Black, Green, Violet Color</li> <li>Non Chlorinated Polymer Coated</li> </ul>			
Packaging			
100 Pieces Per Box 10 Boxes			
10 Boxes per Carton (1,000 Pieces)			
20FCL - 1,300 Cartons (13,000 Boxes)			
40FCL - 2,600 Cartons (26,000 Boxes)			
40HQ - 3,200 Cartons (33,000 Boxes)			
Regulatory Compliance			
MDO 93/42/EEC			
FDA 50H/Class 1			
Standards			
ASTM D6319, D6124, D6 978.05			
EN ISO 374-1 2016			
EN ISO 374-5 2016			
ISO 2859 - 1			
EN 374 - 4 2013			
EN 420 2003 A1,2009			
EN 388 2016 A1,2018			
EN 455 - 2			
Manufacturing Accreditations			
ISO 9001:2015			
ISO 13485:2016			
GMP Certified			

