





EU Declaration of Conformity

European Medical Device Regulation 2017/745

Trade Name:	365 Healthcare
Manufacturer:	Bunzl Retail & Healthcare Supplies Limited
Address:	George House, Unit 6, Delta Park Industrial Estate Millmarsh Lane, Enfield EN3 7QJ United Kingdom

Devices	Single use, Nitrile Examination glove, non-powdered, non-sterile
Product codes	See page 2
Classification	Class I
Rule	5

Declaration

Bunzl Healthcare declares that the products listed on page 2 conform with the relevant provisions of the European Medical Device Regulation 2017/745 including the relevant annexes required to the classification of devices in this declaration.

Applied Harmonised Standards

BS EN ISO 13485:2016
EN 455 Parts 1-4

This EU declaration of conformity is issued under the sole responsibility of the manufacturer;

Designated Representative

Date: 22/07/2020

Signed



Technical, Quality Regulatory Manager
Bunzl Healthcare, London, UK

EU Declaration of Conformity

European Medical Device Regulation 2017/745

Product Code	Product Description	UDI/GS1 Barcode
P2759	NITRILE BLUE PF GLOVE X SMALL	05056003414196
P2760	NITRILE BLUE PF GLOVE SMALL	05056003414219
P2761	NITRILE BLUE PF GLOVE MEDIUM	05056003414233
P2762	NITRILE BLUE PF GLOVE LARGE	05056003414257
P2763	NITRILE BLUE PF GLOVE X LARGE	05056003414271
P2760AF6	NITRILE BLUE PF ACC FREE GLOVES SMALL	05056003413915
P2761AF6	NITRILE BLUE PF ACC FREE GLOVES MEDIUM	05056003413939
P2762AF6	NITRILE BLUE PF ACC FREE GLOVES LARGE	05056003413953
P2763AF6	NITRILE BLUE PF ACC FREE GLOVES X LARGE	05056003413977
PSCR0150(N)	NITRILE BLUE PF GLOVES X SMALL	05056003427363
PSCR0150	NITRILE BLUE PF GLOVES X SMALL	05056003414295
PSCR0151(N)	NITRILE BLUE PF GLOVES SMALL	05056003427387
PSCR0151/A	NITRILE BLUE PF GLOVES SMALL	05056003439700
PSCR0151	NITRILE BLUE PF GLOVES SMALL	05056003414318
PSCR0152(N)	NITRILE BLUE PF GLOVES MEDIUM	05056003427400
PSCR0152/A	NITRILE BLUE PF GLOVES MEDIUM	05056003439717
PSCR0152	NITRILE BLUE PF GLOVES MEDIUM	05056003414332
PSCR0153(N)	NITRILE BLUE PF GLOVES LARGE	05056003427424
PSCR0153/A	NITRILE BLUE PF GLOVES LARGE	05056003439724
PSCR0153	NITRILE BLUE PF GLOVES LARGE	05056003414356
PSCR0154(N)	NITRILE BLUE PF GLOVES X LARGE	05056003427448
PSCR0154/A	NITRILE BLUE PF GLOVES X LARGE	05056003439731
PSCR0154	NITRILE BLUE PF GLOVES X LARGE	05056003414370
PSCR0171	NITRILE WHITE PF GLOVES SMALL	05056003430462
PSCR0172	NITRILE WHITE PF GLOVES MEDIUM	05056003430486
PSCR0173	NITRILE WHITE PF GLOVES LARGE	05056003430509
PSCR0174	NITRILE WHITE PF GLOVES X LARGE	05056003430523
P2740	NITRILE BLUE U'SENSITIVE PF GLOVES SMALL	05056003413830
P2741	NITRILE BLUE U'SENSITIVE PF GLOVES MEDIUM	05056003413854
P2742	NITRILE BLUE U'SENSITIVE PF GLOVES LARGE	05056003413878
P2743	NITRILE BLUE U'SENSITIVE PF GLOVES X LARGE	05056003413892
PSCR0181	NITRILE BLACK PF GLOVES SMALL	05056003434408
PSCR0182	NITRILE BLACK PF GLOVES MEDIUM	05056003419191
PSCR0183	NITRILE BLACK PF GLOVES LARGE	05056003419214
PSCR0184	NITRILE BLACK PF GLOVES X LARGE	05056003401264

Report No. : CA04062
Company : YTY Group
Integra Tower, #19-01, Intermark
348 Jalan Tun Razak
50400 Kuala Lumpur, Malaysia

TEST REPORT

Product Description : Powder Free On Line Chlorinated Nitrile Examination Gloves
Brand Name : N40PSB
Lot No. : Y18234A06A49-52
Colour : Blue
Country of Origin : Malaysia
Size : Medium
Production Date : 22/08/2018
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2000
Testing Period : 12 Feb 2019 – 22 Feb 2019

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 0

Result : Within AQL

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SGS (MALAYSIA) SDN BHD



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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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Company : YTY Group
Integra Tower, #19-01, Intermark
348 Jalan Tun Razak
50400 Kuala Lumpur, Malaysia

TEST REPORT

Product Description : Powder Free On Line Chlorinated Nitrile Examination Gloves
 Brand Name : N40PSB
 Lot No. : Y18234A06A49-52
 Colour : Blue
 Country of Origin : Malaysia
 Size : Medium
 Production Date : 22/08/2018
 vQuantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 12 Feb 2019 – 22 Feb 2019

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	96	98	95	95	97	96	98	96	97	95	97	96	95	96
Length Median: ≥ 240mm	250	252	248	249	250	252	248	247	244	246	247	250	250	249

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Company : YTY Group
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348 Jalan Tun Razak
50400 Kuala Lumpur, Malaysia

TEST REPORT

Product Description : Powder Free On Line Chlorinated Nitrile Examination Gloves
 Brand Name : N40PSB
 Lot No. : Y18234A06A49-52
 Colour : Blue
 Country of Origin : Malaysia
 Size : Medium
 Production Date : 22/08/2018
 Sample Quantity : 26 pieces
 Test Conducted : Force at Break Before Ageing & After Ageing
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 168 hrs
 Testing Period : 12 Feb 2019 – 22 Feb 2019

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
M	1	8.1	8.5
	2	6.9	7.6
	3	7.9	7.1
	4	7.1	8.1
	5	7.1	8.5
	6	7.0	7.4
	7	8.6	8.2
	8	6.7	7.6
	9	7.2	7.5
	10	7.2	6.7
	11	7.0	8.3
	12	6.4	8.1
	13	8.7	7.5
Median		7.1	7.6
Requirement		≥ 6.0	≥ 6.0

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TEST REPORT

Product Description : Powder Free On Line Chlorinated Nitrile Examination Gloves
Brand Name : N40PSB
Lot No. : Y18234A06A49-52
Colour : Blue
Country of Origin : Malaysia
Size : Medium
Production Date : 22/08/2018
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2015
Testing Period : 12 Feb 2019 – 22 Feb 2019

On testing the samples, the following results were obtained:-

SIZE

Average Powder Mass per Glove

M

0.26 mg

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