WE PROTECT PEOPLE
SHIELDGUARD

CERTIFICATE CHECK LIST

PREMIUM
550
MEDICAL
NITRILE GLOVES
• NON STERILE
• POWDER FREE
• CHEMOTHERAPY TESTED

100
Gloves
90 Gloves | XL

	EUROPE	Y/N	ISSUED
No.	Item		
1	CE Trade mark license for EU Market	Y	
2	Declaration of Comformity	Y	
3	EU Representative	Y	
4	EC Type Examination PPE EU Regulation 2016/425	Y	
5	Medical Device Directive 93/42/EEC	Y	
6	EN 455-1	Y	
7	EN 455-2	Y	
8	EN 455-3	Y	
9	EN ISO 374 Part/Type B or A	Y	Type B
10	EN 16523-1 :2015+A (EN 374-1)	Y	
11	EN 374-2	Y	
12	EN 374-3		EN374-1 and En374-3 read as one
13	EN 374-4	Y	
14	EN 374-5	Y	
15	Notified Body	Y	SATRA-in process with SATRA UK- will be out by DEC
16	EN 420 / EN21420:2020	Y	
17	EC 1935/2004 Or EN 1186 - Food Contract	Y	
18	NITRILE TECHNICAL SHEET	N	We only provide spec sheet NOT technical sheet
19	LATEX TECHNICAL SHEET	N	We only provide spec sheet NOT technical sheet
	AMERICA		
No.	Item		
1	FDA Registration	Y	
2	FDA 510k	Y	Our own 510K will be out sometime end Nov 2021, we are using Co-manufacturer 510K at the moment
3	ASTM D-6319-19 (NITRILE)	Y	
4	ASTM D-6124-06	Y	
5	ASTM D-5151-19	Y	
6	ASTM D-6978-05	Y	
7	ASTM D-3578-19 (LATEX)	Y	
	Factory Local Certificate	Y	MALAYSIA RUBBER BOARD (MRB) LICENSE FOR EXPORT
No.	Item		
1	Factory Operation Permit (Rorngor4) - Thai Government	N/A	
2	ISO 9001	N	
3	ISO 13485	Y	
4	ISO 14001	N	
5	GMP	N	
6	ISO 10993 part 5, 10 , 12	Y	

SEAL

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McKINLEY