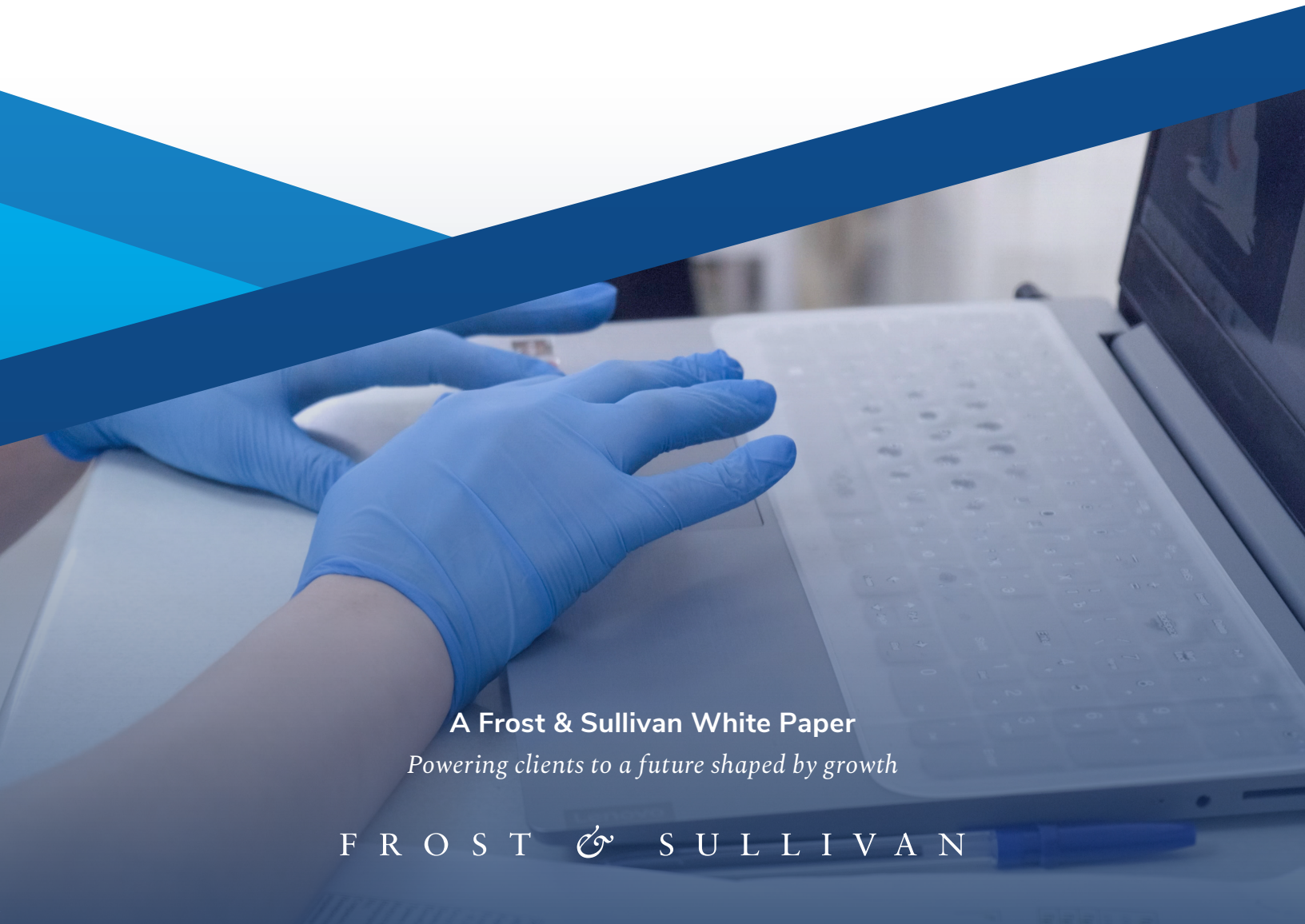
Nitrile Examination Gloves in Europe

An Influx of Inferior Products into the Market



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Introduction

Medical gloves primarily find use as personal protective equipment to prevent healthcare workers from having direct contact with contaminated surfaces, infectious patients, blood and body fluids, or harmful solutions or chemicals. They provide a barrier to protect patients from healthcare workers' potentially contaminated hands. The medical glove industry in Europe follows strict regulations to ensure a high degree of safety for both healthcare workers and patients, with several standards ensuring manufacturers produce gloves that comply with the necessary health and safety requirements.

Despite quality being an important criterion for medical glove acceptance in Europe, concern is increasing about the influx of non-compliant examination gloves into the market, especially during the COVID-19 outbreak. Hence, Frost & Sullivan has taken the initiative to conduct a study to validate this market sentiment.

Study Objective and Methodology

Objective	Conduct lab tests on glove samples from the European market to determine product quality and compliance with required performance standards
Glove type	Nitrile examination gloves
Sample size	22 reputable glove brands with high market share across Europe; 350 glove samples from the same manufacturing lot and of the same size (size M as priority) for each brand
Markets coverage	Germany, Spain, France, Italy, Poland, Portugal, United Kingdom, Ireland
Methodology	• Step 1: Procure the selected 22 glove brands from pharmacies, retailers, or distributors • Step 2: Deliver the glove samples to an accredited testing laboratory (Surgical Materials Testing Laboratory) to conduct performance tests • Step 3: Consolidate and analyse results from lab tests
Performance tests conducted	• BS EN455-1: 2000 Medical gloves for single use—Part 1: Requirements and testing for freedom from holes • BS EN455-2: 2015 Medical gloves for single use—Part 2: Requirements and testing for physical properties • Measurement of glove thickness (cuff, palm, and finger) and glove weight
Fieldwork period	• Glove procurement: May–September 2021 • Glove testing: June–December 2021

Executive Summary

Our study shows that only 9 of the 22 glove brands examined (40%) passed the BS EN455-1 and BS EN455-2 standards, where perforation and force at break (FAB) are the main non-compliance contributors. The results are alarming and require glove importers' and regulators' attention to ensure manufacturer quality adherence.

FIGURE 1: Summary of Results from All Safety and Performance Tests

No.	Product	AQL stated on box	Perforation (AQL 1.5%)	FAB - unchallenged	FAB - challenged	Length	Width
1	Brand B	1.0	✔	✔	✔	✔	✔
2	Brand D	0.65	✔	✔	✔	✔	✔
3	Brand E	1.0	✔	✔	✔	✔	✔
4	Brand I	1.0	✔	✔	✔	✔	✔
5	Brand L	1.5	✔	✔	✔	✔	✔
6	Brand N	NA	✔	✔	✔	✔	✔
7	Brand R	0.65	✔	✔	✔	✔	✔
8	Brand T	0.65	✔	✔	✔	✔	✔
9	Brand V	NA	✔	✔	✔	✔	✔
10	Brand M	1.5	✘	✔	✔	✔	✔
11	Brand P	1.0	✔	✘	✔	✔	✔
12	Brand K	1.5	✔	✔	✘	✔	✔
13	Brand A	1.0	✔	✘	✘	✔	✔
14	Brand G	1.5	✔	✘	✘	✔	✔
15	Brand H	NA	✔	✘	✘	✔	✔
16	Brand J	1.0	✔	✘	✘	✔	✔
17	Brand Q	1.0	✔	✘	✘	✔	✔
18	Brand C	1.5	✘	✘	✘	✔	✔
19	Brand O	0.65	✘	✘	✘	✔	✔
20	Brand S	0.65	✘	✘	✘	✔	✔
21	Brand U	NA	✔	✘	✘	✘	✔
22	Brand F	1.0	✘	✘	✘	✘	✔

Complied to BS EN455-1 and BS EN455-2 standards

AQL = acceptable quality limit

Note:

1. The study sorted samples by compliance level, from highest to lowest.

2. For those brands that comply with the 1.5% AQL perforation standard for examination gloves, the study did not validate whether the more stringent AQL of 0.65% and 1% that 10 brands declare on their packaging are accurate.

Key Takeaways

1. Most glove brands (77%) complied with the perforation standard for examination gloves at an AQL of 1.5%. However, some glove brands claim the lowest AQL of 0.65%, as stated on their packaging, but did not even pass the 1.5% AQL. This information misleads consumers, making them think they are purchasing better quality gloves, for which they are willing to pay more.
2. More than half of the glove brands (12 brands or 55%) failed FAB testing, with most scoring below the required mark for both challenged and unchallenged.
3. Considering dimensions, all glove brands fulfilled the standard requirement for width, while only 2 brands (9%) failed to meet the minimum length limit.
4. Despite common belief, a glove's weight or thickness (cuff, palm, and finger) is not an accurate indicator of its quality. While Brand B and Brand V are among the 5 lightest and 5 thinnest (for most areas), both fully complied with BS EN455-1 and BS EN455-2 standards. In contrast, although Brand F is one of the heaviest and thickest glove brands, it failed most of the BS EN455 standards the study tested.

Glove Perforation

(In accordance with BS EN 455 -1: 2000 Medical gloves for single use—Part 1: Requirements and testing for freedom from holes)

High perforation in examination gloves indicates the presence of many pinholes, which increases the risk of cross-contamination and infection between user and patient, with the BS EN 455-1 standard requiring an AQL of 1.5%. While most medical gloves on the market will achieve this, some specialist gloves will reach an AQL of 1% or 0.65%.

The lab tests revealed that 5 (23%) of the examined glove brands in this study did not achieve a 1.5% AQL, with the suspicion that 3 of them would not even pass an AQL of 6.5%.

FIGURE 2: Results of Perforation Testing for Each Glove Brand (at 1.5% AQL) by Stage

No.	Product	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
1	Brand A	✔				
2	Brand B	-	-	✔		
3	Brand C	-	✘			
4	Brand D	✔				
5	Brand E	-	-	✔		
6*	Brand F	✘				
7	Brand G	✔				
8	Brand H	✔				
9	Brand I	✔				
10	Brand J	-	-	-	-	✔
11	Brand K	✔				
12	Brand L	✔				
13	Brand M	-				
14	Brand N	-	-	✔		
15*	Brand O	✘				
16	Brand P	-	-	-	✔	
17	Brand Q	✔				
18	Brand R	✔				
19*	Brand S	✘				
20	Brand T	✔				
21	Brand U	✔				
22	Brand V	✔				

Note:
- *Indicates testing continued to the next stage.*
* *Suspect the brand would not even pass AQL of 6.5% (hypothetical, not conclusive)*

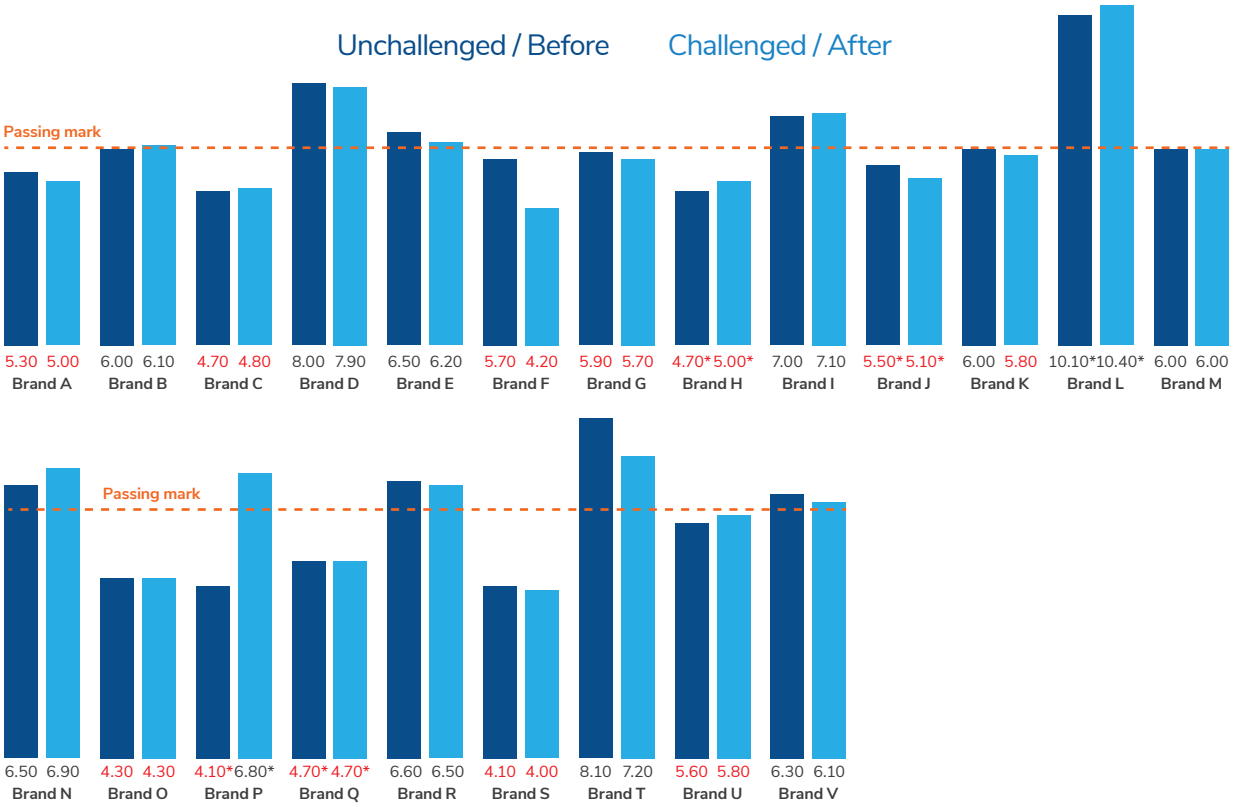
Glove FAB

(In accordance with BS EN 455 - 2: 2015 Medical gloves for single use—Part 2: Requirements and testing for physical properties)

The objective of the FAB test is to determine glove strength, considering shelf life and ageing, to minimise tearing during use.

Our study shows that 12 (55%) of the examined glove brands failed FAB testing, with 10 scoring below the required mark for both challenged and unchallenged, while 1 brand failed following a challenge.

FIGURE 3: Median Results of FAB (Unchallenged/Before and Challenged/After) by Brand



Note:
Figures in red indicate brands that do not comply or scored below the pass mark.
** Indicates results to carefully consider as manufacturing dates were more than 12 months in the past.*

Glove Dimension Measurement

(In accordance with BS EN 455 - 2: 2015 Medical gloves for single use—Part 2: Requirements and testing for physical properties)

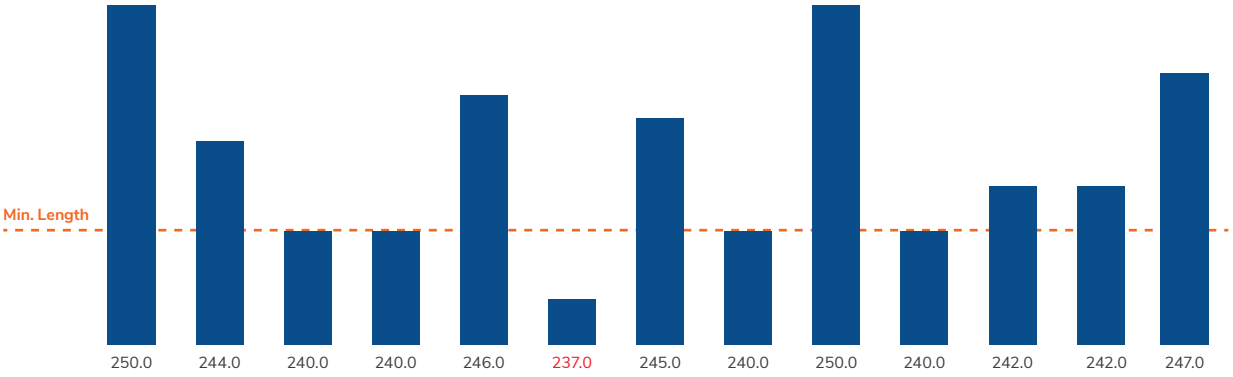
The BS EN 455-2 requires disposable medical gloves to have a minimum length of 240 mm regardless of glove size to ensure sufficient protection. It specifies the following width requirements for disposable medical gloves:

- Extra-small size: ≤80 mm
- Small size: 80 ± 10 mm
- Medium size: 95 ± 10 mm
- Large size: 110 ± 10 mm
- Extra-large size: ≥ 110 mm

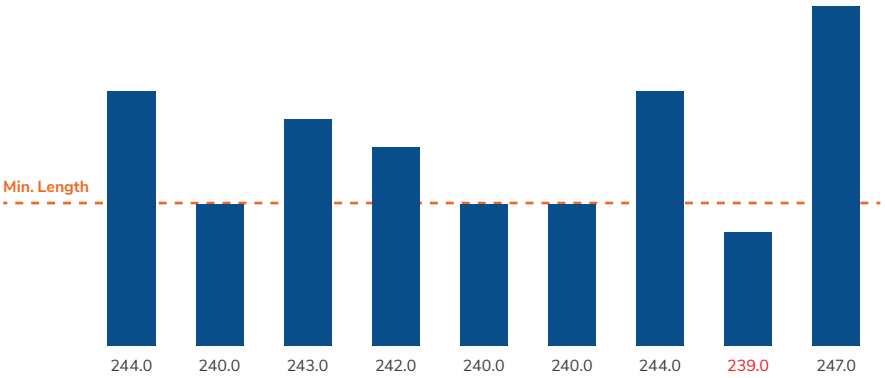
This ensures that the gloves conform with uniform sizing specifications so that users can select the correct size.

Among the 22 brands this study evaluated, 2 did not comply with the minimum length, while all brands met the width requirements for their sizes.

FIGURE 4: Median Dimensions of Length (in mm) for Each Glove Brand



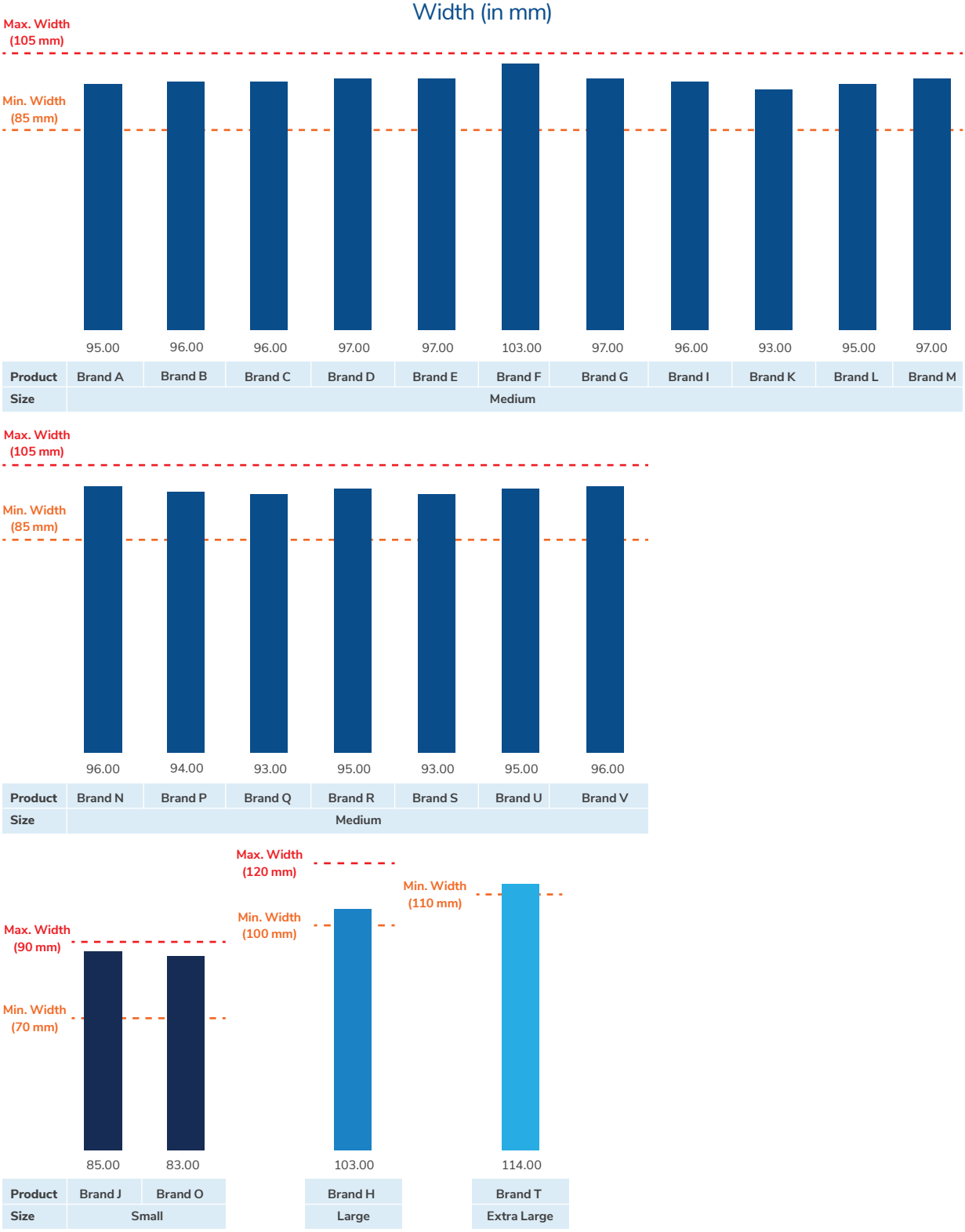
Product	Brand A	Brand B	Brand C	Brand D	Brand E	Brand F	Brand G	Brand H	Brand I	Brand J	Brand K	Brand L	Brand M
Size	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Large	Medium	Small	Medium	Medium	Medium



Product	Brand N	Brand O	Brand P	Brand Q	Brand R	Brand S	Brand T	Brand U	Brand V
Size	Medium	Small	Medium	Medium	Medium	Medium	Extra Large	Medium	Medium

Figures in red indicates 'Does Not Complies' or scored below the passing mark.

FIGURE 5: Median Dimensions of Width (in mm) for Each Glove Brand



Figures in red indicates 'Does Not Complies' or scored below the passing mark.

Mass Measurement and Additional Glove Dimensions

(Additional information the BS EN 455 standards do not specify)

A misconception exists among end users and some glove companies that heavier and thicker gloves are of better quality. Hence, this study requested the testing laboratory to measure the weight and thickness (at cuff, palm, and finger) of the samples and compare the results with the brands' performance in part 1 and part 2 of the BS EN 455 standards.

The lab results revealed that a glove's weight or thickness is not an accurate indicator of glove quality. While Brand B and Brand V are among the 5 lightest and 5 thinnest (for most areas), both fully comply with BS EN455-1 and BS EN455-2 standards. In contrast, although Brand F is one of the heaviest and thickest glove brands, it failed most tested BS EN455 standards. This may be because of ash content, which the heavy weight or high thickness contributes by a high percentage of other chemicals/polyvinyl.

FIGURE 6: Median Glove Weight (in g) for Each Glove Brand

No.	Product	Glove Weight (in g)
1	Brand F	5.76
2	Brand L	4.81
3	Brand T	4.63
4	Brand P	4.10
5	Brand I	3.81
6	Brand D	3.71
7	Brand H	3.69
8	Brand C	3.56
9	Brand K	3.56
10	Brand U	3.51
11	Brand R	3.41
12	Brand J	3.39
13	Brand E	3.33
14	Brand N	3.21
15	Brand O	3.20
16	Brand A	3.19
17	Brand S	3.18
18	Brand V	3.08
19	Brand M	3.02
20	Brand B	2.94
21	Brand G	2.82
22	Brand Q	2.72

Note: Results are sorted based on measurements, from the largest to the smallest value.

FIGURE 7: Median Cuff Thickness (in mm) for Each Glove Brand

No.	Product	Cuff Thickness (in mm)
1	Brand L	0.164
2	Brand F	0.151
3	Brand P	0.138
4	Brand J	0.125
5	Brand C	0.121
6	Brand I	0.118
7	Brand T	0.113
8	Brand D	0.112
9	Brand H	0.112
10	Brand K	0.111
11	Brand U	0.109
12	Brand O	0.109
13	Brand A	0.107
14	Brand R	0.101
15	Brand E	0.101
16	Brand N	0.098
17	Brand B	0.098
18	Brand S	0.094
19	Brand V	0.090
20	Brand M	0.090
21	Brand G	0.084
22	Brand Q	0.081

Note: Results are sorted based on measurements, from the largest to the smallest value.

FIGURE 8: Median Palm Thickness (in mm) for Each Glove Brand

No.	Product	Palm Thickness (in mm)
1	Brand F	0.199
2	Brand L	0.187
3	Brand P	0.153
4	Brand K	0.148
5	Brand O	0.143
6	Brand J	0.142
7	Brand T	0.138
8	Brand C	0.137
9	Brand U	0.137
10	Brand I	0.136
11	Brand H	0.136
12	Brand D	0.134
13	Brand A	0.124
14	Brand R	0.123
15	Brand E	0.119
16	Brand N	0.117
17	Brand S	0.117
18	Brand V	0.117
19	Brand B	0.115
20	Brand M	0.112
21	Brand G	0.100
22	Brand Q	0.096

Note: Results are sorted based on measurements, from the largest to the smallest value.

FIGURE 9: Median Finger Thickness (in mm) for Each Glove Brand

No.	Product	Finger Thickness (in mm)
1	Brand L	0.301
2	Brand F	0.260
3	Brand D	0.251
4	Brand P	0.227
5	Brand E	0.226
6	Brand T	0.217
7	Brand I	0.217
8	Brand U	0.216
9	Brand H	0.208
10	Brand A	0.203
11	Brand R	0.202
12	Brand C	0.198
13	Brand K	0.190
14	Brand J	0.184
15	Brand O	0.183
16	Brand S	0.183
17	Brand V	0.179
18	Brand M	0.178
19	Brand G	0.177
20	Brand N	0.164
21	Brand B	0.162
22	Brand Q	0.159

Note: Results are sorted based on measurements, from the largest to the smallest value.

Final Word

Europe classifies medical gloves (including single-use, surgical gloves, and examination gloves) as medical devices that must comply with the Medical Device Regulation 2017/745, which came into force on 25 May 2017 and became mandatory on 26 May 2021.[1] Any medical gloves that EU countries import or sell must comply with applicable regulations, obtain registration with the country's local authority, and bear the CE mark from an authorised body to prove compliance with those requirements.

Glove importers, regulators, or enforcement agencies do not usually check compliance with medical glove standards for product batches nor periodically while the CE certification is still active. As such, a risk exists for an influx of inferior products into the market, especially when demand for medical gloves is high (e.g., at the beginning of the COVID-19 pandemic) or with a change in contract manufacturer. Glove importers, regulators, or enforcement agencies must consider this trend and ensure that they monitor the quality of medical gloves that enter the market.

1 EU Medical Device Regulation MDR 2017/745, *TÜV Rheinland*

Appendix

The 22 nitrile examination glove brands that this study tested (in alphabetical order):

1. Abena—Gloves Nitrile
2. Abook—Laurel
3. B. Braun Melsungen—Vasco Nitril Soft blue
4. Bericah—Derma Nitryl Soft Nero
5. Bericah—Sensinitryl
6. Celulosas Vascas, Aachen—CV Protection
7. Clini-Lab—Clinisafe Nitrile
8. Didactic—Polysem.medical
9. Fannin—Caressential
10. Med-Comfort—Blue Eco-Plus
11. Medicare Products—NITREX Extra Sensitive
12. Meditrade—Nitril NextGen
13. Mercator Medical—Nitrylex Orange
14. Nacatur International—Med Nitryl Free
15. Nacatur International—Naturex 626 Nitryl Derm
16. Paul Hartmann—Peha-soft Nitrile White
17. Paul Hartmann—Peha-soft Nitrile Fino
18. Rays—Glovely Biosoft Chemical Protection
19. Rays—Glovely Biosoft Stretch Property
20. Sanicen—Sanyc Sensitive Azul
21. Semperit Investments—Sempercare Nitrile
22. WRP Asia Pacific—Dermagrip Nitrile Examination Gloves Ultra LT

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