



CERTIFICATS DE CONFORMITÉ GANTS NITRILES

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NITRILE GLOVES CERTIFICATES OF CONFORMITY



# CERTIFICATE

This is to certify that the product listed below conforms to the requirements of the

**Directives Name** EU 2016/425-PERSONAL PROTECTIVE EQUIPMENT (PPE) Regulation 93/42/EEC - MEDICAL DEVICES DIRECTIVE

**Certificate no.:** [REDACTED] **Date of Expiry:** 03 September 2023

**Date of Issue:** 04 September 2020 **Surv. Due.** 03 September 2021

**Manufacturer :** [REDACTED]

**Description of Products :** Medical Examination Nitrile Gloves & Vinyl Gloves (Disposable)

**Equipment Identification :** AS ABOVE

**Other Certification :** NO

**Standards Applied :** EN 455-1:2020, EN 455-2:2015, EN ISO 374-1:2006+A1:2018, EN ISO 21420:2020, EN ISO 374-5:2016

**Report Reference:** NTLICL/CE/TH9202U-2020

This Report has been Issued by Certiva Limited according to the provision of the Personal Protective Equipment (**European Economic council**). This Report is issued following the assessment of the documentation and implementation of the Quality System in accordance with the provisions of the quoted Conformity Assessment Module of the above directives. The CE Mark may be affixed to the press Personal Protective Equipment the Scope of approvals as described above once the 'EU declaration of conformity' has been signed by the responsible person.



  
**Director**



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**Test Report No.:**

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Test No.	T003	
Material No.	M003	
Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)
1	9.40	10.81
2	10.57	9.36
3	10.07	9.46
4	9.52	9.81
5	10.54	10.51
6	7.25	10.14
7	9.16	10.09
8	8.89	9.62
9	8.24	10.17
10	10.19	7.64
11	10.14	10.79
12	7.60	9.62
13	8.05	8.07
Median result	9.20	9.72
Conclusion	Pass	Pass

Abbreviation: N denotes Newton

Remark:

1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.0

- a) Requirements for all surgical gloves
- b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)
- c) Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)



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Sample photo



M001 – Size S



M002 – Size M



M003 – Size L

- END -