

CERTIFICATE OF CONFORMITY & CERTIFICATE OF ANALYSIS

Brand	BioClean™
Size(s)	7.5
Material	Nitrile
Style	Excell BEXS
Short Description	Gant stérile jetable en nitrile pour salle blanche
Numéro de Lot	25-7038
Numéro de lot de fabrication	N32504702
Date de fabrication	04/2025
Date d'expiration	03/2030

CERTIFICATE OF CONFORMITY

Ansell certifies that the above product is manufactured in accordance with Ansell product specifications and is in conformity with the following standards or normative documents:

Standard/Document Normatif	Résultat
Free from BSE/TSE (EMEA/410/01)	Conforme
Sterilisation – Gamma Irradiation ISO 11137-1	Conforme
PPER (EU) 2016/425	Conforme
REACH REGULATION (EC) No 1907/2006	Conforme
Sampling Plan ISO 2859-1	Conforme

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Propriété	Méthode de test	Spécification	Résultat
Water-Tight Test	EN ISO 374-2	G-1, AQL 1.5, PL2	Conforme
Liquid Particle Count	IEST-RP-CC005.4	N=3, N/A	Conforme
Extractable Ionic Burden	IEST-RP-CC005.4	N=3, N/A	Conforme
Dimension Test	EN420	S-2, 4.0	Conforme
Physical Properties	EN 455-2	S-2, 4.0	Conforme
Force at Break (N)	EN 455-2	≥ 9	Conforme
Packing Conformity check	Internal test method	N/A, N/A	Conforme
Visual Inspection-major	Internal test method	G-1, AQL 2.5	Conforme
Visual Inspection-minor	Internal test method	G1, AQL 4.0	Conforme

Electronically Signed by:

Amy Jones

Manager, QA

Date: 18 September 2025

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