Jan 2026, R 3.0

Eagle Protect, PBC — Product Compliance Statements

Product:	**Derma2 Nitrile Examination Gloves, Powder-free**	
Colour:	Blue	Black
Product Code:	1151202 (S)	1152202 (S)
	1151302 (M)	1152302 (M)
	1151402 (L)	1152402 (L)
	1151502 (XL)	1152502 (XL)

Letter of Guarantee — US Code of Federal Regulations, Title 21, Part 177 (21 CFR 177), Food Contact:

Eagle Protect, PBC, the supplier of the items identified above, hereby confirm that they meet the composition and conditions of use requirements for indirect food additives (polymers) specified in the current US Code of Federal Regulations, Title 21, Part 177 (21 CFR 177).

The composition and conditions of use requirements can be found at the USFDA website address– http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=177.2600 and navigating to the Electronic Code of Federal Regulations, in particular Part 177.2600 (Rubber articles intended for repeated use).

FDA 510(k) Clearance:

Eagle Protect PBC, the supplier of the items identified above, hereby confirm that the product has been issued with an FDA letter of clearance to market the product according to Regulation 21 CFR 880.6250 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.6250), which identifies the product as:

"A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing."

Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove

	Blue colour:	**Black colour:**
Regulatory Class :	Class I, reserved	Class I
Product Code:	LZA, LZC, OPJ, QDO	LZA, LZC, QDO

Certified B Corporation

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California 96150
USA

Eagle Protect PBC is a division of Eagle Direct Ltd

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Allergen Statement:
The manufacturer has confirmed with Eagle Protect, PBC, supplier of the products identified above, that the following listed substances potentially causing allergens or intolerances are not intentionally used or added to the production process:

Milk, Eggs, Fish, Crustaceans, Tree Nuts, Peanuts, Wheat, Soybeans.

PFAS and other Chemicals – Absence Declaration:

Substance:	**Intentionally Added Yes/No**
PFAS (Per- and Poly-fluoroalkyl Substances)	No
PFOS	No
Phthalates	No
Silicone	No
Powder	No
Natural Rubber Latex	No
1,4 Dioxane (CAS #123-91-1)	No
SVHCs (Substance of Very High Concern) as per REACH EC/1907/2006	No

Third Party Audit Statement:
Eagle Protect, PBC, the supplier of the items identified above, hereby confirm that the manufacturer of the products listed has been independently third party audited by APSCA certified auditors, and has current compliance in accordance with the following applicable standards and certifications:

ISO 9001:2015 – Quality Management Systems – Requirements

ISO 13485:2016 & EN ISO 13485:2016 - Quality Management System – Requirements (Medical Devices)

ISO 14001:2015 — Environmental Management Systems

ISO 45001:2018 — Occupational Health & Safety Management Systems

BRC GS - Global Standard for Consumer Products – Personal Care and Household, Issue 4, Grade: AA, for: Compounding, Dipping and Packing of Non-sterile Nitrile Gloves packed in plastic bag and carton (Examination and General Purpose Use)

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Sedex Members Ethical Trade Audit (SMETA) **—** 4 Pillar Social Audit (including Environmental and Business Ethics).

Worldwide Responsible Accredited Production (***WRAP***) Certification, **Gold Compliance —** Internationally recognized social, ethical and sustainable compliance standards, including Prohibition of Forced and Child Labor*.

*A separate Eagle Protect, PBC statement on the prohibition of Forced and Child Labor is available on request.

These confirmations shall continue until revoked in writing by Eagle Protect, PBC. Conformance documentation is proprietary to Eagle Protect, PBC and its Suppliers but may be provided for audit purposes on request.

K Row
Sustainability/Quality
Eagle Protect, PBC

January 2026