COMMONWEALTH OF PENNSYLVANIA
PENNSYLVANIA COMMERCIAL ITEM DESCRIPTION (PCID)

Patient Exam Gloves

PCID NO.1170
Eff. 14 Feb 2022

This Pennsylvania Commercial Item Description (PCID) covers minimum requirements for Standard Patient Exam Gloves and Specialty Patient Exam Gloves as part of the Commonwealth Personall Protective Equipment (PPE) inventory program. Product shall conform to the following specification, unless stated otherwise in the bid invitation or purchase order.

1.0 Definitions

1.1 Standard Gloves: Designed to help protect, and prevent contamination, between caregivers/examiners and patients
1.2 Specialty Gloves: Designed for higher hand protection when moderate or small amounts of fentanyl is visible or suspected

2.0 General Requirements

2.1 Nitrile polymer (Shall not contain natural rubber latex)
2.2 Exam grade
2.3 non-sterile
2.4 Disposable: intended to be discarded after use
2.5 Powder-free
2.6 Waterproof
2.7 Unpaired and ambidextrous
2.8 Color: to be specified in bid document(s)
2.9 Texture: to be specified in bid document(s)

3.0 Classification

3.1 Designated FDA Class 1 (general controls); 510(k) required
3.2 Standard (non-specialty) gloves with one or both of the following FDA product codes:
    3.2.1 LZA: Polymer Patient Examination Glove (includes nitrile, polyurethane, etc.)
    3.2.2 FMC: Patient Examination Glove
3.3 Specialty gloves with the following FDA product code:
    3.3.1 QDO: Fentanyl and other Opioid Protection Glove

4.0 Use Cases

4.1 Situations in which the caregiver/examiner has potential for coming into contact with a patient’s blood, bodily fluids, secretions, excretions, and items that are soiled by bodily fluids
4.2 Cases of direct exposure
    4.2.1 Contact with mucous membrane (e.g., oral, or nasal mucosa)

4.2.2 Contact with non-intact skin
4.2.3 Potential presence of highly infectious and dangerous organism
4.2.4 Epidemic or emergency use cases
4.2.5 IV/needle insertion and removal
4.2.6 Discontinuation of a needle/venous line
4.3 Cases of indirect exposure
4.3.1 Emptying emesis basins
4.3.2 Handling and cleaning of instruments
4.3.3 Handling soiled patient linens
4.3.4 Handling patient waste
4.3.5 Cleaning up spills of body fluids
4.4 Cases of exposure requiring specialty examination gloves
4.4.1 Contact with hazardous/toxic material (e.g., chemotherapy agent, fentanyl)
4.4.2 Pre-hospital patient care
4.4.3 Routine law enforcement duties, investigations, evidence collection, special operations, and decontamination

5.0 Acceptable Quality Level (AQL)
5.1 Manufacturer shall maintain a quality management system certified to ISO 13485:2016 or ISO 9001:2015, and shall provide supporting documentation with bid proposal
5.2 Product shall be rejected and/or deemed non-compliant if packaging is compromised
5.3 Shall have an AQL rating of 2.5 per ASTM D6319. This means that a particular lot of gloves will have defects (e.g., pinholes) not to exceed 2.5% of product tested

6.0 Applicable Standards
6.1 Shall meet the requirements specified in:
6.1.1 ASTM D6319: Standard Specification for Nitrile Examination Gloves for Medical Application; or
6.1.2 EN 455 (Parts 1 to 4): Medical gloves for single use
6.2 For bacteria and/or viral resistance:
6.2.1 EN ISO 374-5 for Bacteria and Fungi; or
6.2.2EN ISO 374-5 for Virus
6.3 For Fentanyl protection and resistance:
6.3.1 ASTM D6978: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
6.3.2 No breakthrough after exposure for a minimum of 240 minutes
6.4 Supporting Documentation shall be provided with bid proposals, from a certified independent party, indicating that requirements for these Applicable Standards have been met

7.0 Related Standards
7.1 ASTM D7103: Standard Guide for Assessment of Medical Gloves
7.2 NFPA: Standard on Protective Clothing for Emergency Medical Operations
7.3 ANSI 105-2016: Hand Protection Classification

8.0 Sizes

8.1 Standard gloves in accordance with ASTM D6319

Designation	Small	Medium	Large	X-Large	XX-Large	Tolerance
Width (mm)	80	95	110	120	130	+/- 10 mm
Length (mm)	220	230	230	230	230	min

8.2 Specialty gloves in accordance with ASTM D6319 and NIOSH recommendations

Designation	Small	Medium	Large	X-Large	XX-Large	Tolerance
Width (mm)	80	95	110	120	130	+/- 10 mm
Length (mm)	270	270	270	270	270	min

9.0 Gauges

9.1 Ranges shall be indicated in the bid solicitation

9.2 Measured at middle fingertip in accordance with ASTM D6319

10.0 Packing

10.1 The packing and packaging shall be in accordance with the industries standard practice in a manner to ensure carrier acceptance and safe delivery to destination

10.2 Does not contain any material likely to impair product quality and use

10.3 Specific pack, box, and case sizes will be indicated in the bid invitation

11.0 Labeling

11.1 Inner Packaging (box/pack)

11.1.1 Shall be in English

11.2.1 Shall include name of manufacturer or distributor, including the address or country of origin.

11.3.1 Shall indicate name of material (e.g., Nitrile).

11.4.1 Shall indicate type of product (e.g., “powder-free nitrile examination gloves”)

11.5.1 Shall indicate net quantity of contents (e.g., “100 gloves, packaged by weight”)

11.6.1 Shall indicate size, color, and gauge (thickness)

11.7.1 Shall indicate lot number

11.8.1 Shall indicate expiration date

11.9.1 Shall indicate directions for use, including a statement that product is “single use only” or “not for reuse” (or similar)

11.10.1 Shall have indication that product does not contain any natural rubber latex

11.11.1 Shall indicate adherence to applicable ASTM standard

11.12.1 For specialty gloves, shall indicate tested for use with and intended for exposure to hazardous chemicals, to include fentanyl

11.2 Outer Packaging (case)

11.2.1 Shall be in English

11.2.2 Shall include name of manufacturer or distributor, including the address or country of origin.

11.2.3 Shall include Customer Order Number and Barcode for Customer Order Number

11.2.4 Shall include Customer Material Master Number and Barcode for Customer Material Master Number

11.2.5 Shall include complete item description including name of material, type of product, size, color, and gauge

11.2.6 Shall indicate inner pack quantity, number of inner packs, total case quantity

11.2.7 Shall indicate lot number

11.2.8 Shall indicate expiration date

12.0 Storage

12.1 Product shall be left in their original cartons and/or individual packages until needed. They should be stored on a shelf to avoid damage from water leaks or compression damage that can occur when stepped on or rolled over by equipment. Do not break the seal on a glove package until ready for use, as gloves may degrade more readily upon exposure. Check before use for signs of degradation (e.g., discoloration, pinholes), which would render them unsuitable for their intended purpose. Gloves not stored properly in their packaging may also be subject to contamination, rips, and/or tears, which could put users at risk of contact with harmful substances or blood borne pathogens. Dispose if there are any signs of degradation or damage.

12.2 Avoid storing within the same area as chemical liquids, vapors, or gases.

12.3 Store in a controlled environment for humidity and that allows for air flow or some method of ventilation

12.4 Store in a water-resistant manner. This includes the original packaging and shipping cartons, a moisture-free environment, along with other measures to protect from humidity and water.

12.5 Avoid exposure to direct sunlight

12.6 Do not store in airtight containers

13.0 Shelf Life

13.1 Strict adherence to the expiration date on the packaging and product shall be followed.

13.2 Product shall have a minimum expiration date of at least two (2) years from date of delivery to the warehouse and not to exceed five (5) years from date of manufacture.

14.0 Sampling, Inspection and Testing

14.1 Samples may be requested during the bid evaluation phase and/or after a contract has been entered into with the awarded supplier

14.2 The Commonwealth reserves the right to inspect product either in-house or through an approved independent third party

14.3 The Commonwealth reserves the right to test product through an approved independent third party. Should testing be required, random sampling shall be in accordance with ISO Standard 2859-1

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