fisherbrand

Fisherbrand™ Nitrile Cleanroom Gloves

Validation Pack

fisher scientific
part of Thermo Fisher Scientific



This validation pack provides specifications, technical information, Certificates of Irradiation and Analysis, a BSE/TSE Declaration, and Endotoxin Report for Fisherbrand™ Class 100 and Class 10 Cleanroom Gloves.

Product Data Sheets

Certifications

Fisherbrand

Nitrile Cleanroom Class 100 Non-Sterile Gloves

Fisherbrand™ Nitrile Cleanroom Class 100 Non-Sterile Gloves are ISO 5 Cleanroom compatible or higher. Their textured fingertips and soft feel offer superior handling and comfort in the cleanroom environment.

They are manufactured from 100% nitrile butadiene rubber that provides reliable, durable, and comfortable hand protection during demanding cleanroom applications.

Fisherbrand Nitrile Cleanroom Class 100 Non-Sterile Gloves are processed in an NEBB-Certified Class 10 cleanroom environment (FED STD 209E).

For critical cleanroom environments
For industrial use only

Physical Properties

- Ambidextrous
- Double chlorinated processing
- Powder and accelerator free
- Not made with natural rubber latex
- Textured fingers
- Beaded cuff

Material	100% Nitrile Butadiene Rubber
Color	White
Tensile Strength	Min 15 MPa
Elongation	600%
Non-Volatile Residue	<3.0 microgram/sq.cm
ESD Parameters:*	• Surface Resistance ≤10E100 hms/sq. • Decay Time ≤0.5 Seconds • Tribo Charge ≤20 Volts
Length	300 mm/12 in.
Thickness	5 mil Palm/7 mil Finger
Shelf Life	5 Years from Date of Manufacture
AQL	1.5

Tested per ASTM D-257

Dimension (mm)	XS	S	M	L	XL
Length	300	300	300	300	300
Palm Width	75 to 79	80 to 89	90 to 99	100 to 109	110 to 116
Single Wall Thickness	0.01	0.01	0.01	0.01	0.01
Finger Thickness	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3
Palm Thickness	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2
Cuff Thickness	7 ± 2	7 ± 2	7 ± 2	7 ± 2	7 ± 2

Cleanliness Properties

Particle and extractable testing done in accordance with IEST-RP-CC005.4.

Liquid Particle Count	<2,200 Particle Counts Cumulative at 0.5 micron	IEST-RP-CC005.4
Organics	Silicone Oil Free	IEST-RP-CC005.4
Ionic Burden	Microgram/sq.cm	IEST-RP-CC005.4
Fluoride	<0.040	
Phosphate	<1.000	
Nitrate	<1.200	
Sodium	<0.060	
Magnesium	<0.005	
Potassium	<0.060	
Chloride	<1.400	
Sulphate	<1.000	
Bromide	<0.060	
Lithium	<0.0005	
Copper	<0.0005	

Packaging Information

- 100 pieces/sealed inner cleanroom bag
- 10 outer cleanroom bag/case liner
- 1 case liner/case (1,000 pieces)

The traceability numbers (lot and batch numbers) are shown on the outer cleanroom bag and case.

Quality and Regulatory Standards

Complies with the requirements of the Glove Standard EN420:2003+A1:2009, the European Medical Gloves Standard EN455 (Parts 1, 2, and 3), and EN374-1:2016, EN374-5 (VIRUS).

Manufactured in a facility with ISO 9001:2015, ISO 17025:2017, ISO 13485:2016, and ISO 14001:2015 certifications, and compliant with PPE Regulation (EU) 2016/425 and GMP certification-MS1514:2009.

Recommended for use in Class 100 (ISO 5 or higher) cleanrooms.

Made in Malaysia.

Sampling Information

ISO 2859-1:1999(E) Sampling Procedures for Inspection by Attributes – Part 1

Ordering Information

Fisherbrand Nitrile Cleanroom Gloves, Class 100, Ambidextrous, Non-Sterile

Cat. No.	Size	Quantity
12-892-006E	XS	1,000/Case
12-892-006A	S	1,000/Case
12-892-006B	M	1,000/Case
12-892-006C	L	1,000/Case
12-892-006D	XL	1,000/Case

Visit **fishersci.com** or **fishersci.ca** to learn more.

Fisherbrand

Nitrile Cleanroom Class 10 Non-Sterile Gloves

Fisherbrand™ Nitrile Cleanroom Class 10 Non-Sterile Gloves are ISO 4 Cleanroom compatible or higher. Their textured fingertips and soft feel offer superior handling and comfort in the cleanroom environment.

They are manufactured from 100% nitrile butadiene rubber that provides reliable, durable, and comfortable hand protection during demanding cleanroom applications.

These ambidextrous gloves are processed in an NEBB-Certified Class 10 cleanroom environment (FED STD 209E).

For critical cleanroom environments
For industrial use only

Physical Properties

- Ambidextrous
- Double chlorinated processing
- Powder and accelerator free
- Not made with natural rubber latex
- Textured fingers
- Beaded cuff

Material	100% Nitrile Butadiene Rubber
Color	White
Tensile Strength	Min 15 MPa
Elongation	600%
Non-Volatile Residue	<2.5 microgram/sq.cm
ESD Parameters:*	• Surface Resistance ≤10E100 hms/sq. • Decay Time ≤0.5 Seconds • Tribo Charge ≤20 Volts
Length	300 mm/12 in.
Thickness	5 mil Palm/7 mil Finger
Shelf Life	5 Years from Date of Manufacture
AQL	1.5

Tested per ASTM D-257

Dimension (mm)	XS	S	M	L	XL	2XL
Length	300	300	300	300	300	300
Palm Width	75 to 79	80 to 89	90 to 99	100 to 109	110 to 116	117 to 122
Single Wall Thickness	0.01	0.01	0.01	0.01	0.01	0.01
Finger Thickness	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3
Palm Thickness	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2
Cuff Thickness	7 ± 2	7 ± 2	7 ± 2	7 ± 2	7 ± 2	7 ± 2

Cleanliness Properties

Particle and extractable testing done in accordance with IEST-RP-CC005.4.

Liquid Particle Count	<800 Particle Counts Cumulative at 0.5 micron	IEST-RP-CC005.4
Organics	Silicone Oil Free	IEST-RP-CC005.4
Ionic Burden	Microgram/sq.cm	IEST-RP-CC005.4
Fluoride	<0.007	
Phosphate	<0.25	
Nitrate	<0.35	
Sodium	<0.04	
Magnesium	<0.003	
Potassium	<0.0400	
Chloride	<0.20	
Sulphate	<0.30	
Bromide	<0.025	
Lithium	<0.0004	
Copper	<0.0004	

Packaging Information

- 100 pieces/sealed inner cleanroom bag
- 10 outer cleanroom bag/case liner
- 1 case liner/case (1,000 pieces)

The traceability numbers (lot and batch numbers) are shown on the outer cleanroom bag and case.

Quality and Regulatory Standards

Complies with the requirements of the Glove Standard EN420:2003+A1:2009, the European Medical Gloves Standard EN455 (Parts 1, 2, and 3), and EN374-1:2016, EN374-5 (VIRUS).

Manufactured in a facility with ISO 9001:2015, ISO 17025:2017, ISO 13485:2016, and ISO 14001:2015 certifications, and compliant with PPE Regulation (EU) 2016/425 and GMP certification-MS1514:2009.

Recommended for use in Class 10 (ISO 4 or higher) cleanrooms.

Made in Malaysia.

Sampling Information

ISO 2859-1:1999(E) Sampling Procedures for Inspection by Attributes – Part 1

Ordering Information

Fisherbrand Nitrile Cleanroom Gloves, Class 10, Ambidextrous, Non-Sterile

Cat. No.	Size	Quantity
12-892-004A	XS	1,000/Case
12-892-004B	S	1,000/Case
12-892-004C	M	1,000/Case
12-892-004D	L	1,000/Case
12-892-004E	XL	1,000/Case
12-892-004F	2XL	1,000/Case

Visit **fishersci.com** or **fishersci.ca** to learn more.

Fisherbrand

Nitrile Cleanroom Class 100 Sterile Gloves

Fisherbrand™ Nitrile Cleanroom Class 100 Sterile Gloves are ISO 5 Cleanroom compatible or higher. Their textured fingertips and soft feel offer superior handling and comfort in the cleanroom environment.

They are manufactured from 100% nitrile butadiene rubber that provides reliable, durable, and comfortable hand protection during demanding cleanroom applications.

Fisherbrand Nitrile Cleanroom Class 100 Sterile Gloves are processed in an NEBB-Certified Class 10 cleanroom environment (FED STD 209E). They're sterilized by a minimum of 2.5Mrad Gamma radiation and assured for intact pouch for five years from date of sterilization.

For critical cleanroom environments
For industrial use only

Physical Properties

- Hand-specific, anatomical shape
- Powder and accelerator free
- Not made with natural rubber latex
- Textured fingers
- Beaded cuff

Material	100% Nitrile Butadiene Rubber
Color	White
Tensile Strength	Min 15 MPa
Elongation	600%
Non-Volatile Residue	<3.0 microgram/sq.cm
ESD Parameters:*	• Surface Resistance ≤10E100 hms/sq. • Decay Time ≤0.5 Seconds • Tribo Charge ≤20 Volts
Length	300 mm/12 in.
Thickness	5 mil Palm/7 mil Finger
Shelf Life	5 Years from Date of Manufacture
AQL	1.5

Tested per ASTM D-257

Dimension (mm)	6.0	6.5	7.0	7.5	8.0	8.5	9.0	10.0
Length	300	300	300	300	300	300	300	300
Palm Width	77 ± 5	83 ± 5	89 ± 5	95 ± 5	102 ± 5	108 ± 5	114 ± 5	120 ± 5
Single Wall Thickness	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Finger Thickness	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3	14 ± 3
Palm Thickness	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2	10 ± 2
Cuff Thickness	9 ± 2	9 ± 2	9 ± 2	9 ± 2	9 ± 2	9 ± 2	9 ± 2	9 ± 2

Cleanliness Properties

Particle and extractable testing done in accordance with IEST-RP-CC005.4.

Liquid Particle Count	<2,200 Particle Counts Cumulative at 0.5 micron	IEST-RP-CC005.4
Organics	Silicone Oil Free/DOP/ Amides Detected	IEST-RP-CC005.4
Ionic Burden	Microgram/sq.cm	IEST-RP-CC005.4
Fluoride	<0.040	
Phosphate	<1.000	
Nitrate	<1.200	
Sodium	<0.060	
Magnesium	<0.005	
Potassium	<0.060	
Chloride	<1.400	
Sulphate	<1.000	
Bromide	<0.060	
Lithium	<0.0005	
Copper	<0.0005	

Packaging Information

- 1 pair/pouch,
- 10 pouches/pack
- 20 packs/case
- 200 pairs/case

The traceability numbers (lot and batch numbers) are shown on the outer cleanroom bag and case.

Quality and Regulatory Standards

Complies with the requirements of the European Medical Gloves Standard EN455 (Parts 1, 2, and 3) and EN374-1:2016, EN374-5 (VIRUS).

Manufactured in a facility with ISO 9001:2015, ISO 17025:2017, ISO 13485:2016, ISO 14001:2015 certifications, compliant with PPE Regulation (EU) 2016/425 and GMP certification-MS1514:2009.

Recommended for use in Class 100 (ISO 5 or higher) cleanrooms.

Made in Malaysia.

Sampling Information

ISO 2859-1:1999(E) Sampling Procedures for Inspection by Attributes – Part 1

Ordering Information

Fisherbrand Nitrile Cleanroom Gloves, Class 100, Hand-Specific, Sterile

Cat. No.	Size	Quantity
12-892-007A	6.0	200/Case
12-892-007B	6.5	200/Case
12-892-007C	7.0	200/Case
12-892-007D	7.5	200/Case
12-892-007E	8.0	200/Case
12-892-007F	8.5	200/Case
12-892-007G	9.0	200/Case
12-892-007H	10.0	200/Case

Visit **fishersci.com** or **fishersci.ca** to learn more.

Certificate of Irradiation

9639713

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 03-Jun-2021 **MY01S12574092-1-1**

This is to certify that Synergy Sterilisation Rawang (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

Order Information

Account Number:	**101042**
Synergy Health Sales Part Reference:	**1134519**
Customer Reference Number:	**BSB/7977/21**
Product Description:	**Class 100 Processed 300mm (12") Hand Specific Gamma Sterilized Cleanroom Nitrile Gloves**
Validation Reference:	**R210007 Rev.1**
Quantity Received:	**193**
Customer Minimum Specification kGy:	**25.0**
Customer Maximum Specification kGy:	**40.0**

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang , MALAYSIA
VAT Number: 000878280704
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EN ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

Other Process Details:

LOT NO	SIZE	QTY
EP-1249/0060-EP1249/0091	6.0	32
EP-1249/0404-EP1249/0428	6.5	24
EP-1249/0776-EP1249/0779	7.0	3
EP-1249/1391-EP1249/1405	7.5	15
EP-1249/2025-EP1249/2026	8.0	2
EP-1249/2369-EP1249/2371	8.5	3
EP-1319/0001-EP1319/0025	6.0	25
EP-1319/0060-EP1319/0070	6.5	11
EP-1319/0153-EP1319/0160	7.0	8

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang , MALAYSIA
VAT Number: 000878280704

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Certificate of Irradiation

Date Issued: 03-Jun-2021 MY01S12574092-1-1

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EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

	EP-1319/0431-EP1319/0500 9.0 70

Irradiation Data

Date and Time of Irradiation:	03-Jun-2021 04:56
Reference Dose Range kGy:	31.0 - 32.2
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	37.2

Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS Company

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang , MALAYSIA
VAT Number: 000878280704

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Declaration BSE/TSE

Declaration BSE/TSE Free Products

PART NUMBER: 12-892-006
PRODUCT DESCRIPTION: FISHERBRAND™ NITRILE CLEANROOM GLOVE, CLASS 100, 300MM, AMBIDEXTROUS, NON-STERILE

Transmissible Spongiform Encephalopathies (TSE)
Bovine Spongiform Encephalopathy (BSE)

TSE includes BSE, the bovine form occurring in cows (mad-cow-disease), the scrapie disease in sheep, as well as the human form: the variant-Creutzfeldt-Jakob-Disease (vCJD).

The products are manufactured completely from synthetic or manufactured materials and do not contain any raw materials produced from, or substances derived from animal origin. Moreover, these products are not derived from specific-risk materials as defined in European Commission Decision 97/534/EC.

The manufacturing process does not use any ingredient of animal origin nor do our products come in contact with animal products during storage and transportation. The products are free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

Sincerely

Mohamed Halil

Certificate of Analysis

fisher scientific
part of Thermo Fisher Scientific

Fisher Scientific Company L.L.C.
300 Industry Drive
Pittsburgh, PA 15275
Tel: 724-517-2400
Fax: 724-517-1546
www.fishersci.com

Fisher Catalog Number: 12-892-006

Product Description: Fisherbrand™ Nitrile Cleanroom Glove, Class 100, 300mm, Ambidextrous, Non-sterile

Date: 24/05/2021

Size: S, M, L & XL

CERTIFICATE OF ANALYSIS

NON-VOLATILE RESIDUE DETERMINATION (USING IPA)

NVR Determination: Using Mettle Toledo instrument

Parameter (ug/cm2)	SIZE			
	S	M	L	XL
NVR	1.62	1.79	1.38	1.66

Method: IES-RP-CC005.4

FTIR DETERMINATION

FTIR Determination: Using FTIR instrument model FTIR-8400

Parameter	SIZE			
	S	M	L	XL
Amide	Negative	Negative	Negative	Negative
DOP	Negative	Negative	Negative	Negative
Silicone Oil	Negative	Negative	Negative	Negative

Method: IES-RP-CC005.4

This Certificate has been compiled with data that has been provided by the manufacturer of the product. Fisher Scientific channel has not independently verified such data.

Denise Pollum

Quality Assurance Specialist
Fisher Scientific Company L.L.C

10/13/2021

Date

Endotoxin Report

INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE
Building 19, SIRIM Complex
1, Persiaran Dato' Menteri, Section 2, P. O. Box 7035
40700 Shah Alam, Selangor Darul Ehsan, MALAYSIA
Tel: 603 - 5544 6953 / 6960 Fax: 603 - 5544 6988
Website: www.sirim.my

TEST REPORT

REPORT NO: R 032/22/B19/91	PAGE: 1 of 2

Sample : Disposable glove

Reference standard / Method of Test : European Pharmacopoeia 8.0 (EP 2.6.14. Bacterial Endotoxin) Turbidimetric Kinetic Method

Description of Sample : Received one (1) sample with the following identification for testing:

1. Product name : **Nitrile 300mm handspecific sterile gloves**
   Quantity : **10 pairs**
   Appearance : **Natural white, handspecific, Size 8.0**

Date Received : 3 January 2022

Date Test Started : 7 January 2022

Job No. : J 032/22

Issue Date : 11 January 2022

Approved signatories,

(MOHD KHAIRUL AZWAN AHMAD)
MJMM 0481
Analyst,
Industrial Biotechnology Research Centre,
SIRIM Berhad.

(MOHD FAIRUZUDDIN FAIZAN M YUSOFF)
Reviewer,
Industrial Biotechnology Research Centre,
SIRIM Berhad.

MS ISO/IEC 17025
TESTING
SAMM NO.676

Endotoxin Report *(cont.)*

TEST REPORT

REPORT NO: R 032/22/B19/91	PAGE: 2 of 2
This report is NOT a Quality Assurance Certificate NOR an Approval Permit. This report refers only to samples submitted by the customer to SIRIM Berhad and tested by SIRIM Berhad. This report shall not be reproduced, except in full and shall not be used for advertising purposes by any means or forms without written approval from President & CEO of SIRIM Berhad.	

Results:

Endotoxin test was carried out on pooled extracts derived from 10 pairs of gloves of the same batch. Bacterial endotoxin content of the sample is shown below:

Product name	Quantity	Appearance	Detected Endotoxin (EU/pair of gloves)
Nitrile 300mm handspecific sterile gloves	**10 pairs**	**Natural white, handspecific, Size 8.0**	**3.01**

Notes:

**EU – Endotoxin unit*

***Microbiological quality control limits (Based on BS EN 455-3:2015, Clause 4.3):*

-Endotoxin content shall not exceed the limit of 20 EU per pair of gloves.

Endotoxin Report *(cont.)*

THE CONDITIONS RELATING TO THE USE OF THE INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE TEST REPORT

1. A Test Report will be issued in respect of Testing Services conducted and shall related only to the sample actually tested. SIRIM Berhad makes no warranty whatsoever and the Applicant shall not represent in any manner that any duplication or mass production of the Product is same as the Sample actually tested or that SIRIM Berhad has tested any of the duplicated or mass produced Product.

2. The Test Report shall not be amended, changed, varied or modified in any manner whatsoever by the Applicant or otherwise.

3. If the Test Report is to be furnished to any third party or to the public, each such Test Report shall be furnished in full, legible and in its entirety.

4. The Test Report shall not be reproduced and shall not in any event be used for any advertising purposes or whatsoever without written approval from the President & Chief Executive of SIRIM Berhad of No. 1, Persiaran Dato' Menteri, Building 5, Section 2, P. O. Box 7035, 40700 Shah Alam, Selangor Darul Ehsan.

5. Customer (Applicant/Manufacturer/Factory, etc.) is not permitted to use any SIRIM Berhad, other SIRIM Berhad's subsidiaries logo on packaging, sample's manual, technical specification, brochures/flyers or any other means.

6. If such approval is obtained from the President & Chief Executive, the Applicant may only include the phrase, "A sample of this product has been tested by SIRIM Berhad ... (Test Report No) ... (dated) ... (for what test) ... (to which standard)"or such similar words which stress that only the Sample was actually tested. This phrase shall only be used for the purpose of product advertisement or product promotion (eg; brochures). For avoidance of doubt, the statement shall not be used on the sample and packaging of the sample.

7. In the event there is an investigation from a Government Regulatory Agency concerning the applicant's Test Report, SIRIM Berhad may disclose the information pertaining to the Test Report for purposes of such investigation.

8. Further or in the alternative, it is strictly forbidden to represent in any manner whatsoever that SIRIM Berhad and/or other SIRIM's subsidiaries has endorsed, approved or validated the Product of the Applicant in any manner whatsoever.

9. In the event the applicant is found in breach of this provision, SIRIM Berhad and/or other SIRIM's subsidiaries without prejudice to any other rights and remedies may take whatever action necessary including but not limited to:

   a) Informing and placing a notice in the media;
   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whatsoever related to the Applicant, whether subsidiary or otherwise;
   d) Instructing the Applicant to withdraw and recall the advertisement, statement or document in question and advertise a clarification and apology to SIRIM Berhad and/or other SIRIM's subsidiaries twice in a national publication of SIRIM Berhad's choice at the Applicant's sole cost; and
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.

10. Certified true copies of the Test Report may be issued upon request by the applicant upon payment of the relevant fee.

11. Corrections to test report shall only be allowed within 6 months from issuance date of the Test Report of the relevant fee and shall be limited to maximum 3 times, after either case whichever occurs earlier, a new Test Report shall be issued and replace the previous one (having error(s) or lack of information) with relevant fee. Issuance of Supplementary Report to the original Test Report shall be for the followings:

    a) Misprints and typo errors;
    b) Missing technical information;
    c) Test data not reported;
    d) Mistake in reporting of test data.

12. Any amendment requested from customers on the test report issued shall be in writing.

13. SIRIM reserves the right in its sole discretion to terminate or modify this permission.

(Revision 1.3.2020)

Fisherbrand™ Nitrile Cleanroom Gloves Validation Pack

Distributed by Fisher Scientific. Contact us today:

In the United States
Order online: fishersci.com
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In Canada
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Call customer service: 1-800-234-7437

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