Ontario

Ministry of Health

Assistive Devices Program (ADP)
5700 Yonge Street, 7th Floor
Toronto ON M2M 4K5

Tel: 416 327-8804
Toll free: 1 800 268-6021
Fax: 416 327-8192

Application for Equipment Listing
Pressure Modification Devices

Note: All sections must be completed for each product.

Section 1 – Manufacturer

Name of Manufacturer

Address

Unit Number	Street Number	Street Name	PO Box

City/Town	Province	Postal Code

Section 2 – Distributor

Name of Distributor

Contact Person

Last Name	First Name

Address

Unit Number	Street Number	Street Name	PO Box

City/Town	Province	Postal Code

Telephone Number ext.	Fax Number	Email Address

Section 3 – Device

1. Name of Device

2. ◯a) Medical Device Establishment Licence (MDEL) Number for Class 1 devices

OR

◯b) Medical Device Licence Number for Class 2, 3 or 4 devices

3. If the product/device is sold in the United States, provide:

a) Copy of the premarket notification (510 K) submitted to the Food and Drug Administration of the United States (FDA).

◯Provided ◯Not Applicable, (provide explanation):

b) Copy of the FDA approval letter.

◯Provided ◯Not Applicable, (provide explanation):

4. Type of device (please check all appropriate boxes)

☐Compression Garments for Hypertrophic Scar Management ☐Compression Garments for Lymphedema Management

☐Compression Sleeves for Lymphedema Management ☐Sequential Extremity Pump for Lymphedema Management

5. Has the device been sold to the public for a minimum of two (2) years?

◯Yes ◯No

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6. If you do not have an Ontario based distributor, are you able to deliver the device/product to the client within two (2) days of an order?

◯Yes ◯No (explain delivery policy):

7. a) Was any formal testing done on the device, including safety and effectiveness testing?

◯Yes (attach documentation outlining scientific research, studies and client evaluations)

◯No (provide explanation regarding how safety and efficiency have been determined):

b) Has the device been tested using the RAL GZ 387 guidelines for assessment for pressure modification devices?

◯Yes (provide a copy of the test results)

◯No

c) Provide completed and signed **Statement of Support for Device Listing – Form 4619-87** from four (4) health professionals who work in different settings.

8. State any contraindications and precautions for use of the device/product.

9. Does the warranty for breakage and tearing meet the ADP minimum requirement?

a) Compression garments – 30 days minimum requirement	◯Yes	◯No	◯Not Applicable
b) Compression sleeves – 90 days minimum requirement	◯Yes	◯No	◯Not Applicable
c) Sequential Extremity Pumps and Accessories – 1 year minimum requirement	◯Yes	◯No	◯Not Applicable

10. Does the Manufacturer/Distributor hold a minimum of $2 million liability insurance for the product in question?

◯Yes

◯No (explain why):

11. Do you provide a training program for health professionals and fitters?

◯Yes (provide a copy of the course outline)

◯No (indicate how you ensure proper assessment and fitting of your product):

Section 4 – Certification and Signatures

I, as a signing officer of the manufacturer/distributor, certify that the above information is complete and true.

Last Name	First Name	
Position Title	Signature	Date (yyyy/mm/dd)

Please return the completed for with the original signature to:

Program Coordinator, Pressure Modification Devices Category
Assistive Devices Program
5700 Yonge Street, 7th Floor
Toronto ON M2M 4K5

Thank you for your cooperation