Health Canada / Santé Canada

PRODUITS THÉRAPEUTIQUES / THERAPEUTIC PRODUCTS

APPLICATION FOR A NEW MEDICAL DEVICE LICENCE

(disponible en francais)

1. DEVICE CLASSIFICATION

☐ Class II ☐ Class III ☐ Class IV

2. DEVICE NAME (as it appears on label)

[Note: this is the device name for which the licence will be issued]

3. APPLICATION HISTORY

Has this device been previously authorized for sale in Canada under the Investigational Testing or Special Access provisions of the Regulations?

Yes ☐ No ☑

If yes, please provide the authorization number or the device identification number: _____

Does this device licence application cross reference a previously Notified device or a device with a Notice of Compliance?

Yes ☐ No ☑

If yes, please provide the device identification number : _____

NAME AND ADDRESS OF MANUFACTURER AS IT APPEARS ON THE LABEL

[Note: this is the name and site to which licence will be issued]

Company Name	VIAMED LIMITED
Street Address/P.O. Box	15 STATION ROAD, CROSS HILLS
City	KEIGHLEY
Province/State	WEST YORKSHIRE
Postal/Zip Code	BD20 7DT
Country	UNITED KINGDOM
Contact Name and Title:	
Telephone No.: +44 1535 634542 Fax No.: +44 1535 635582	
E-Mail Address:	

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5. **MAILING ADDRESS FOR REGULATORY CORRESPONDENCE (if different from Item 4)**
Note: (i) The licence will be issued to the Company named in Item 4 but will be sent to the Company shown below if different. (ii) The Company named below must be authorized by the manufacturer named in Item 4 to submit an application on their behalf. See the Authorization of Contact form for details.

Company Name:	
Street Address/P.O. Box City Province/State Postal/Zip Code Country	
Contact Name and Title:	
Telephone No.:	Fax No.:
E-Mail Address:	

6. **LICENCE APPLICATION TYPE (check one only)**

Single Device	
Medical Device Group	
Medical Device Family	✓
Medical Device Group Family	
Test Kit	
System	

7. **PREFERRED NAME CODE: (xxAAA)**

8. **IS THIS DEVICE A NEAR PATIENT *IN VITRO* DIAGNOSTIC (IVDD)?** Yes☐ No☑

IS THIS IVDD SOLD FOR HOME USE? Yes☐ No☑

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9. DEVICE USAGE CATEGORY

(73) Anaesthesiology		(84) Neurology	
(74) Cardiovascular		(85) Obstetrics & Gynaecology	
(76) Dental		(86) Ophthalmology	
(77) Ear, Nose & Throat		(87) Orthopaedics	
(78) Gastroenterology & Urology		(89) Physical Medicine	
(79) General & Plastic Surgery		(90) Radiology/Imaging	
(80) General Hospital	✓		

FOR IVDDs ONLY

(75) Chemistry		(83) Microbiology	
(81) Haematology		(88) Pathology	
(82) Immunology		(91) Clinical Toxicology	

10. DOES THIS DEVICE CONTAIN A DRUG? Yes☐ No☑

(Note: this question does not apply to IVDDs)

If yes

Brand /Trade Name of Drug:
Active Ingredient:
Drug Manufacturer:
Applicable Drug Identification Number (if any):

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11. PURPOSE/INTENDED USE:

A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented: ***(Note: Failure to supply an appropriate level of detail may result in the application being rejected.)***

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12. DEVICE DETAIL

Please provide the following information, as applicable to licence application type, and where applicable for each component device, part or accessory.

Name of Device, Components, Parts and/or Accessories as per product label	Device Identification Number if previously assigned	Model or catalogue number

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CLASS II DEVICES ONLY

NAME OF THE CLASS II DEVICE (as listed in Item 2)

13. LIST OF STANDARDS COMPLIED WITH IN THE MANUFACTURE OF THE DEVICE

14. **I, the Manufacturer of this device, hereby attest that (☐ I have) (☐ I do not have) objective evidence to establish that this device meets the safety and effectiveness requirements set out in the *Medical Devices Regulations*, Part 1, Sections 10 - 20, inclusive. If applicable, I attest that this medical device is Y2K compliant.**

15. **I, the Manufacturer of this device, hereby attest that (☐ I have) (☐ I have not) met all the labelling requirements set out in the *Medical Devices Regulations*, Part 1, Section 21 (1) (a) through (g) inclusive.**

16. **In the case of a near patient IVDD, I, the Manufacturer of this device hereby attest that investigational testing of this device (☐ has been) (☐ has not been) conducted using human subjects representative of the intended user and under conditions similar to the intended conditions of use of the device.**

17. **If this Device contains a drug and it does not have a Drug Identification Number, I the Manufacturer of this device attest that the (☐ drug meets) (☐ drug does not meet) acceptable standards of safety, efficacy and quality.**

I hereby certify that the information provided on this application is correct, complete and in accordance with all relevant sections of the *Medical Devices Regulations*.

Name of Signing Official: _____

Signed: _____ **Date:** _____

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CLASS III DEVICES ONLY

NAME OF THE CLASS III DEVICE (as listed in Item 2)

18. In addition to items 1 to 12, of the Device Licence Application, please indicate (✔) which of the relevant information requirements listed below, are included as attachments to this application. For details regarding content and format, please refer to the guidance document "Preparation of a Premarket Review Document for Class III and IV Device Licence Application".

Executive summary	
Table of contents	
Background, which includes Device Description, Design Philosophy, and Marketing History	
Summary of Safety and Effectiveness Studies, which includes List of Standards, Method of Sterilization, Summary of Studies, and Bibliography	
Near Patient Diagnostic Device Testing Results (if applicable)	
Labelling material	

19. If this Device contains a drug and it does not have a Drug Identification Number, I the Manufacturer of this device attest that the (☐ drug meets) (☐ drug does not meet) acceptable standards of safety, efficacy and quality.

I hereby certify that the information provided on this application and in any attached documentation is correct, complete and in accordance with all relevant sections of the *Medical Devices Regulations*.

Name of Signing Official: _____

Signed: _____ **Date:** _____

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CLASS IV DEVICES ONLY

NAME OF THE CLASS IV DEVICE (as listed in Item 2)

20. In addition to items 1 to 12, of the Device Licence Application, please indicate (✔) which of the relevant information requirements listed below, are included as attachments to this application. For details regarding content and format, please refer to the guidance document "Preparation of a Premarket Review Document for Class III and IV Device Licence Application".

Executive summary	
Table of contents	
Background, which includes Device Description, Design Philosophy, and Marketing History	
Risk Assessment	
Quality Plan	
Device Specific Detailed Information, which includes Material Specifications, Manufacturing Process Specifications, and List of Standards	
Safety and Effectiveness Studies	
Required information for any biological material (if applicable)	
Near Patient Diagnostic Device Testing Results (if applicable)	
Labelling material	

21. If this Device contains a drug and it does not have a Drug Identification Number, **I the Manufacturer of this device attest that the (☐ drug meets) (☐ drug does not meet)** acceptable standards of safety, efficacy and quality.

I hereby certify that the information provided on this application and in any attached documentation is correct, complete and in accordance with all relevant sections of the *Medical Devices Regulations*.

Name of Signing Official: _____

Signed: _____ **Date:** _____

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THERAPEUTIC PRODUCTS

AUTHORIZATION OF CONTACT

(disponible en francais)

(✔ application type)

This form authorizes the person named in Section B to submit this application for : ☐ a new device licence; ☐ an amended device licence; ☐ investigational testing; on behalf of the company identified in Section A.

Section A

I hereby authorize the person named in Section B to submit this application for: ☐ a new device licence; ☐ an amended device licence; ☐ investigational testing; to the Minister on my behalf. The Medical Devices Bureau will accept either this form or a signed letter of authorization on company letterhead.

Name: _____

Title: _____

Company: _____

Telephone Number: _____ **Fax Number:** _____

Signature: **Date:**

Section B

I hereby accept the responsibility to submit this application for: ☐ a new device licence; ☐ an amended device licence; ☐ investigational testing; to the Minister by the person named in Section A. The Medical Devices Bureau will accept either this form or a signed letter of authorization on company letterhead.

Name: _____

Title: _____

Company: _____

Telephone Number: _____ **Fax Number:** _____

Signature: **Date:**

Medical Devices Bureau
Room 1605, Statistics Canada Main Building
Tunney's Pasture, Address Locator: 0301H1
Ottawa, Ontario
K1A 0L2