# Device Product Labels

Sample English product labels that can be adapted for a device study appear on the next page. These labels appear in English only. As stated in section 86 of Canada’s Medical Device Regulations state that the labels should be set out in both official languages. Please find the regulation and the name of an approved translator below.

Section 86. No person shall import or sell a medical device for investigational testing unless the device has a label that sets out

1. the name/address of the manufacturer;
2. the name of the device;
3. the statements “Investigational Device” and “Instrument de recherche”, or any other statement, in English and French, that conveys that meaning;
4. the statements “To Be Used by Qualified Investigators Only” and “Réservé uniquement à l’usage de chercheurs compétents”, or any other statement, in English and French, that conveys that meaning; and
5. in the case of an IVDD, the statements “The performance specifications of this device have not been established” and “Les spécifications de rendement de l’instrument n’ont pas été établies”, or any other statement, in English and French, that conveys that meaning.

**\*\* Note: Labels are designed to be printed on Avery 5164 shipping labels.**

[TRANSLATOR NAME/CONTACT INFORMATION]

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| Manufacturer Name  Manufacturer Address  Manufacturer Address  **Device name**  Protocol Code or ID/No de protocole:  Participant #/No du participant: Visit #/No de visite:  Investigator Name/Nom de l’enquêteur:  FOR CLINICAL USE ONLY  Caution: Investigational Device - To be used by Qualified Investigators Only.  The performance specifications of this device have not been established.  POUR UTILISATION CLINIQUE UNIQUEMENT  Instrument de recherche. Réservée seulement à l’usage des chercheurs qualifiés. Les spécifications de rendement de l’instrument n’ont pas été établies. |  | Manufacturer Name  Manufacturer Address  Manufacturer Address  **Device name**  Protocol Code or ID/No de protocole:  Participant #/No du participant: Visit #/No de visite:  Investigator Name/Nom de l’enquêteur:  FOR CLINICAL USE ONLY  Caution: Investigational Device - To be used by Qualified Investigators Only.  The performance specifications of this device have not been established.  POUR UTILISATION CLINIQUE UNIQUEMENT  Instrument de recherche. Réservée seulement à l’usage des chercheurs qualifiés. Les spécifications de rendement de l’instrument n’ont pas été établies. |
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