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***Note to file***
***Note au dossier***

| Application Information / Information de soumission | |
|---|---|
| *Licence Name/Nom de l'homologation:<br>**SWAB COVID-19** | Application Number/Numéro de soumission<br>**314006** |
| Licence # / # de l'homologation:<br>**0** | Application Type/Type de soumission:<br>**Interim Order** |
| Manufacturer/Fabricant:<br>**8083851 CANADA INC. OPERATING AS PAMA MANUFACTURING** | Company ID/Identificateur d'entreprise:<br>**118638** |
| Risk Class:<br>**2** | Rationale: |
| *Licence Type/Type d'homologation:<br>**Single Device** | Rationale: |

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

**"The intended use for this device is self-evident to the intended user, therefore an intended use statement is not necessary for which the medical device is manufactured, sold or represented, as stated in Regulation 10(h) of the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19"**

| OEM Licence Information | |
|---|---|
| OEM Licence Name : | OEM Manufacturer : |
| OEM Intended Use and/or Indications for Use | |

| COVID-19 Medical Device & Manufacturer Details | |
|---|---|
| Class of Device | Class 1 |
| Intended Use of Device (Section 4(1)(f)) | "The intended use for this device is self-evident to the intended user, therefore an intended use statement is not necessary for which the medical device is manufactured, sold or represented, as stated in Regulation 10(h) of the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19" |

| Device Name | Identifier | GMDN Code | PNC Code |
|---|---|---|---|
| Swab COVID-19 | SWB-0005<br>SWB-0007<br>SWB-0009 | 62723 | 80RYI |
| | | | |
| | | | |
| | | | |

| Reason for Change | | Comment(s) |
|---|---|---|
| Change to classification of a device | ☐ | |
| Manufacturer name change | ☐ | |
| License name change | ☐ | |
| Device name change | ☐ | |
| Change to the purpose/indication of license | ☐ | |
| Addition of device(s) | ☐ | |
| Deletion of device(s) | ☐ | |

Interim Order Amendment

| Reason for Change | | Comment(s) |
|---|---|---|

| | | |
|---|---|---|
| Change in name and/or address of the Private Label Manufacturer | ☐ | |
| Private Label License name change | ☐ | |
| Private Label Device name change | ☐ | |
| Addition of device(s) | ☐ | |
| Deletion of device(s) | ☐ | |

Manufacturer needs to add three products (as indicated by device identifiers above). New identifiers are being created for traceability associated with the repackaging of devices under the PAMA Label. These three identifiers are related to "packaing and labelling process" as indicated in correspondence with the manufacturer. The Sterilization process remains the same for all swabs.

## ***Certificate Screening Checklist:***

| | |
|---|---|
| Cert # (new): | Cert Revisions / Comments (If Applicable): |
| Cert. # (old): | |
| Replacing Existing Cert on File (Y/N): | |

| Criteria | conforms | Comments/info for MDS |
|---|---|---|
| Issued to full name of manufacturer as it appears on application/licence and label. | ☐ | |
| Issued to complete civic address matching application/licence and label. | ☐ | |
| Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282 | ☐ | |
| Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution. | ☐ | |
| Activities include "manufacture" or "production" Activities include "design" or "development and development" for class III/IV devices. | ☐ | |
| Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers. | ☐ | |
| Auditing Organisation is Authorized or Recognized | ☐ | |
| Statement of Authorization or Recognition. | ☐ | |
| Field labelled "Effective Date" | ☐ | |
| Field labelled "Expiry Date" | ☐ | |
| Validity period ≤ 3 years | ☐ | |
| Unique identification code labelled "certificate number" or "certification document number" | ☐ | ☐ new ☐ revised |
| Name, title, and signature of certification authority | ☐ | |
| Pagination (page x or y) included on all pages . All pages present. | ☐ | |
| Method to verify validity | ☐ | |

**Screening Decision**

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***Note au dossier***

| | |
|---|---|
| **Accept** | |
| **Liem Whelan**<br>Device Licensing Services Division<br>Medical Devices Bureau | **Date**: April 23rd, 2020 |

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Check GMDN

| GMDN Name | GMDN Code | GMDN Description | Issue | Action for Screener | Regulatory Action | Reference Material |
|---|---|---|---|---|---|---|