Health Canada / Santé Canada

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

| Application Information / Information de soumission | |
|---|---|
| *Licence Name/Nom de l'homologation:<br>**1COPY COVID-19 QPCR KIT** | Application Number/Numéro de soumission<br>**312777** |
| Licence # / # de l'homologation:<br>**0** | Application Type/Type de soumission:<br>**Interim Order** |
| Manufacturer/Fabricant:<br>**1DROP INC.** | Company ID/Identificateur d'entreprise:<br>**151664** |
| Risk Class:<br>**3** | Rationale:<br>**Class III by IVDD Rule 2(b)(i)** |
| *Licence Type/Type d'homologation:<br>**Test Kit** | Rationale: |

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

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

**1copy™ COVID-19 qPCR Kit is an In-Vitro Diagnostic medical device for qualitative analysis of E gene and RdRp gene for coronavirus (COVID-19) in extracted RNA from sputum, nasopharyngeal swab and oropharyngeal swab of patients with suspected respiratory infections.**

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

| 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) | ☐ | |

| 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 13485:2003 or 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 | ☐ | |

| **ISO 13485 Quality Management System Certificate Screening** | |
|---|---|
| Cert. # (new): | Cert. # (old) : |
| Cert revisions: | |
| | |
| First (most prominent) and full name on cert. matches application/licence, and label. | Effective date of registration. Field is identified as "Effective Date" |
| Address on cert, matches application, licence, and label. | Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date". |
| Standard is (CAN/CSA) ISO 13485:2003 or 2016 | Validity period <= 3 years. |
| Scope includes "manufacture" or "production". Scope includes "design" (fr. conception) for Class III-IV. | Certificate contains unique certificate #.<br>New Revised |
| Scope is unambiguous and covers app. device. Scope does not contain specific product names / models / numbers or licence numbers. Reference to attachment is acceptable. | Name, title, and signature of certification authority. |
| Registrar is recognized. | Number of additional sites appearing on certificate: |
| SCC logo CMDCAS reference are present. | All pages of certificate are present. |

| **COVID-19 Medical Device & Manufacturer Details** | |
|---|---|
| Class of Device | Class III |
| Intended Use of Device (Section 4(1)(f)) | 1copy™ COVID-19 qPCR Kit is an In-Vitro Diagnostic medical device<br>for qualitative analysis of E gene and RdRp gene for coronavirus (COVID-19) in extracted RNA from sputum, nasopharyngeal swab and oropharyngeal swab of patients with suspected respiratory infections. |

| Device Name | Identifier | GMDN Code | PNC Code |
|---|---|---|---|
| 1copy COVID-19 qPCR | M21MD100C | 88UJH | 64747 |

| | | | |
|---|---|---|---|
| Kit | | | |
| | | | |
| | | | |
| | | | |
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| | | | |

| 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) | ☐ | |

***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** | |
|---|---|
| **Accept** | |
| **Liem Whelan**<br>Device Licensing Services Division<br>Medical Devices Bureau | **Date**: March 27th, 2020 |

Health Canada Santé Canada

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

Check GMDN

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