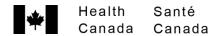
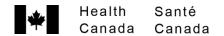


Medical Devices Directorate

| | | | | | _ | | | | | |
|------------------------------------|------------------------------|-------------------------|--------------------------|------------------|-------------------------------------|---------------------------|------------|-----------|-----------------------------|------------------|
| | | | Applicati | on Informat | ion | | | | T | |
| Application #: 312777 | : | Licence Name: 1COPY COV | /ID-19 ∩PCI | P KIT | | | | | Application Type: | Device Class: |
| Licence #: | | 1001 1 001 | וט וט עו ט | IX IXII | | | | | Ü | 3 |
| 0 | | | | | | | | | | |
| Manufacturer: 1DROP INC. | | | | | | Company ID: 151664 | | | | |
| | | | | | | 101001 | | | | |
| | | DL | SD Appl | ication Valid | datio | n | | | | |
| Risk Class & | | Licence Type 8 | k Rationale: | Special Substanc | ces: | | | _ [| Application Form | nat: |
| IVDD Rule 2(| b)[i] | Test Kit | | | | | | ▼ | HC | ▼ |
| | | 1 | Amendm | ent Manageme | ent | | | | | |
| Fee Category | • | | | Reason for Amer | ndmen | t: | | | | |
| | | | | | | | | | | - |
| | | | ▼ | | | | | | | |
| | | | Rundl | e Information | | | | | | |
| Bundle Ration | nalo: | | | | | | | | | |
| Duriule Italion | iaic. | ▼ | Related App Bundle table | | | (| Create/N | /lodify | Financial Bundle | Info |
| | | | Bundle table | included? == | | | | | | |
| | | | | | | | | | | |
| | - | | Submission | on Completen | | | | | | |
| MDR | Requirement | | | | Α | D | N/A | _ | tes/Commen | |
| 32 | Application Forn | n | | | V | \Box | | | IO Authoriza of information | |
| | | | | | | _ | | For | | on request |
| 32 | Submission Pres | sentation (ToC | C, Cover Let | ter, Exec | V | | | | | |
| 22/2 //) | Summary) | | | | | | | | | |
| 32(3a/4a) | Device Descripti form) | ion (as it relate | es to device | listing in | V | | | | | |
| 32(3j/4p) | QMS Certificate | MDSAP/CSA | -ISO 13485 | ·2016 | П | ΙП | V | | | |
| 32(3g/4o) | Labelling – 21(1 | | 100 10100 | | | <u>-</u> - | | | | |
| | | | | | V | | | | | |
| | | | DLSD Re | ecommendation | on | | | | | |
| Γ | Incomple | | | | | | | | | 7 |
| Į. | moompic | | | | | | | | | |
| Rejection F | Rationale: | | | | | | | | | |
| | | | | | | | | | | |
| Notes/Com | | L | | | | | | | | |
| Section 4(1)(b), 4(1)(i), 4(2)(b), | | | | | Date: March 19 th , 2020 | | | | | |
| | | | | | | De | ile. Maich | 19", 2020 | | |
| | Bureau of Licensing Services | | | | | | | | | |
| Medical Devic | ces Directorate | Pavia | w Division | – DLSD Comn | aunia | otion | | | | |
| Daview Di | delen Cenerana A | | w Division | - DESD COMM | numic | ation | | | | |
| Keview DIV | vision Screener Ac | Suon: | | | | | | | | |
| Review Div | vision Screener Re | esponse: | | | | | | | | |
| _ | | | | | | | | | | |
| | | | | | | | | Da | ite: | |
| | | | | _ | | | | | | |
| Review Division Screener | | | | | | | | | | |



| Technical Screening (Review Division) | | | | | |
|---|--|------------|-------------------------------|--------------------|--|
| Proposed reviewer: | | | Estimated Review Time (days): | Review Complexity: | |
| | | • | | V | |
| Review Components Review Required Deficient | | | Commer | nts | |
| | | s III + IV | · | | |
| General Application Organization | | | | | |
| Device Description | | | | | |
| Marketing History | | | | | |
| Standards & Conformity Declaration | | | | | |
| Analytical Performance | | | | | |
| Physical & Chemical Bench Testing | | | | | |
| Electrical & Radiation Safety | | П | | | |
| Software Validation & Verification | | | | | |
| Biocompatibility & Pyrogenicity | | | | | |
| Sterilization, Packaging, &Shelf Life | | | | | |
| Animal Testing | ╅ | | | | |
| Stability | | | | | |
| Product Stability (Shelf Life) | | | | | |
| Usability | | | | | |
| Clinical Studies | | | | | |
| Bibliography | | | | | |
| Near patient IVDD | | | | | |
| Labelling | | | | | |
| | Clas | ss IV | | | |
| Risk Assessment | | | | | |
| Quality Plan | | | | | |
| Biological Safety | | | | | |
| Manufacturing Process | | | | | |
| Process Validation | | | | | |
| Note to the Reviewer (e.g. predicate, reference, cautions, directions) Foreign Review incl. SBD? | | | | | |
| Recommendation | | | | | |
| | | | | | |
| Bundle Update/Modification – To DLS manager | | | | | |
| Rejection Rationale: | | | | | |
| Technical Screening Deficiencies: | | | | | |
| 1. | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

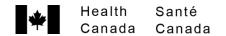




| DLSD Deficiencies | | | | | |
|--|-------------------|------------------|---------------------------|--|--|
| | | | | | |
| Over Paid Fee | | | | | |
| Deficiency | | | | | |
| Section 4(1)(b), No Classification ruling from manufacturer for their product Section 4(1)(i), "An attestation by the applicant that documented procedures are in place in respect distribution records, complaint handling, incident reporting and recalls" has not been included with trapplication. Section 4(2)(b), "A list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls the device in those countries" has not been included with the application. | | | | | |
| Certificate Screening Checklist: | | | | | |
| ☐ MDSAP ☐ Certif | ficate Previously | Validated | | | |
| Cert # (new): | | Cert Revisions / | Comments (If Applicable): | | |
| Cert. # (old): Replacing Existing Cert on File (Y/N): | | | | | |
| Criteria | | Conforms | Comments/info for MDS | | |
| First (most prominent) and full nam | | | | | |
| matches application/licence, and la Address on cert. matches application label. | | | | | |
| Standard is (CAN/CSA) ISO 13485:2 | 003 or 2016. | | | | |
| Scope includes "manufacture" or " Scope includes "design" (fr. Concep III-IV. | | | | | |
| Scope is unambiguous and covers a Scope does not contain specific promodels / numbers or licence numb to attachment is acceptable. | duct names / | | | | |
| Registrar is recognized. | | | | | |
| SCC logo and CMDCAS references a | re present. | | | | |
| Effective date of registration. Field "Effective Date" | is identified as | | | | |
| Expiry date. Field is identified as "E Date", or "Recertification Due Date" | | | | | |
| Validity period ≤ 3 years. | | | | | |
| Certificate contains Unique Certific | | | | | |
| Name, title, and signature of certifi authority. | cation | | | | |
| All pages of certificate are present. | | | | | |



| (| 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 | | | | |
| <u> </u> | Statement of Authorization or Recognition. | | | | |
| _ | Field labelled "Effective Date" | | | | |
| l | Field labelled "Expiry Date" | | | | |
| _ | Validity period ≤ 3 years | | | | |
| | Unique identification code labelled "certificate | | ☐ new ☐ revised | | |
| _ | number" or "certification document number" | | □ Hew □ FeViseu | | |
| - | Name, title, and signature of certification authority | | | | |
| | Pagination (page x or y) included on all pages . All | | | | |
| pages present. | | | | | |
| ١ | Method to verify validity | | | | |
| | ISO 12405 Quality Managaman | t Cartam C | 1.00 | | |
| | ISO 13485 Quality Managemen | it System C | | | |
| Cert. 7 | # (new): | | Cert. # (old) : | | |
| Cert i | revisions: | | | | |
| | | | | | |
| | | | | | |
| | (most prominent) and full name on cert. matches | | Effective date of registration. Field is identified | | |
| pplic | eation/licence, and label. | | as "Effective Date" | | |
| | | | Expiry date. Field is identified as "Expiry" or | | |
| Addr | ess on cert, matches application, licence, and label. | | "Expiry date". Or "Recertification due date". | | |
| | | | | | |
| tand | ard is (CAN/CSA) ISO 13485:2003 or 2016 | | Validity period <= 3 years. | | |
| | | | | _ | |
| | Scope includes "manufacture" or "production". Scope includes | | Certificate contains unique certificate #. | | |
| tr. co | onception) for Class III-IV. | | New Revised | | |
| | | | | _ | |
| | e is unambiguous and covers app. device. Scope does not con t names / models / numbers or licence numbers. Reference to attachment | | Name, title, and signature of certification | | |
| ccepta | | | 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 | 1copy [™] COVID-19 qPCR Kit is an In-Vitro Diagnostic | | | |
| 4(1)(f)) | 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. | | | |

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