V-0.1/17.04.2020

Covid-19 Medical Devices: Regulatory Ecosystem Guide

I. Medical equipment

1) *Covid-19 Diagnostic Test Kits*

Substantive	a) Reverse-transcriptase Polymerase Chain Reaction-based b) Rapid testing (antibody-based)
Approval Process	Two-stage process PCR based a) ICMR/US FDA/CE approval required. Apply for ICMR approval here: https://icmr.nic.in/sites/default/files/upload_documents/Kit_Validation_v2.pdf b) CDSCO license to manufacture/ import as relevant. Apply to SUGAM portal for login credentials and validation to submit documents online: https://cdscoonline.gov.in/CDSCO/homepage Rapid-testing a) ICMR approval required. Link to apply: https://icmr.nic.in/sites/default/files/upload_documents/Kit_Validation_v2.pdf b) CDSCO license to manufacture/ market/ testing as relevant. Apply to SUGAM portal for login credentials and validation to submit documents online: https://cdscoonline.gov.in/CDSCO/homepage In cases of delays or issues with the CDSCO office, write to DGCI with Invest India's reference.[1]
Logistics/ Infrastructure	a) Testing Labs: ICMR validated. i) Link to existing testing lab network and collection points for samples: https://covid.icmr.org.in/index.php/testing-facilities

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc3MA==

	ii) How to apply to become eligible as testing lab under ICMR: https://icmr.nic.in/sites/default/files/upload_documents/Criteria_for_initiation_additional_COVID19_testing_laboratories.pdf b) Advisory on procurement for reagents: https://icmr.nic.in/sites/default/files/upload_documents/Advisory_for_Reagents_TestingLabs_v1.pdf c) Transport for the sample: under ICMR. d) Scaling up production: Each state government has made provisions to apply for temporary passes. Request you to please seek out your state policy department's movement pass. Each state also has a dedicated control room manning the movement of essentials. Please refer to the following link for your state's details: https://www.investindia.gov.in/bip/resources/state-and-central-control-rooms
Additional products for testing	a) VTM kits b) Swabs for collection of samples c) Probes: enzyme that bind on to the DNA segment signaling presence of viral material d) Primer
Regulating body	a) ICMR – for test validation b) CDSCO – for licensing
Clarifications sought	a) Blanket approval has been provided to USFDA and CE approved kit. No clarification regarding marketing procedure. b) CDSCO hasn't published a list of companies to whom importing license has been granted c) No specifics for RNA extraction and VTM kits available.

Detailed instruction on how to fill applications on the SUGAM portal[2] (Applicable for all CDSCO application processes)

a) *Register on portal with verified login* credentials to access the Online Form Submission.
b) After logging in, fill all mandatory fields under user profile including member details, wholesale license details and contact details.
c) After successfully updating User Profile, user may submit application into the system.
d) Fill Permission Owned/ Historical Data or Form Submission.
e) Fill information under Permission Owned/ Historical Data if applicant holds permissions (Registration Certificate and Import License) in hard copy issued in the year 2012 or later.
f)
   i. For registration certificate: if user us applying for endorsement case of re-registration case for RC then fill details related to previous RC first before applying for Form 40 under Form Submission menu.
   ii. For import license: if applying for endorsement case or renewal of import license, then fill details of previous import license before applying for form 8 under Form submission menu.
g) Under Form Submission:

   Select Form 40 (for getting RC number) or Form 8 (for import license number) depending upon the license being applied for,

h)
   i. Application for Form 40:

- User can apply for Form 40 for three cases i.e. **Fresh, Endorsement** and **Re-registration**.
- Before applying for **Endorsement** or **Re-Registration** case, user must fill the previous RC details first in **Permission Owned/Historical** data menu.
- User should fill all the required (mandatory) fields to fill the form.
- After filling the form till first preview, user can modify the form.

[2] https://cdscoonline.gov.in/CDSCO/QuickNotes

- Once user moves to the checklist, user will not be able to modify the form .So, user should provide all correct entries.
- If user do not fill the complete application in one go, then application will be saved in **Saved As Draft** mode.
- To view application in **Saved as Draft** mode, **click on Menu Form Submission Saved Applications**.

ii. Application for **Form 8:**

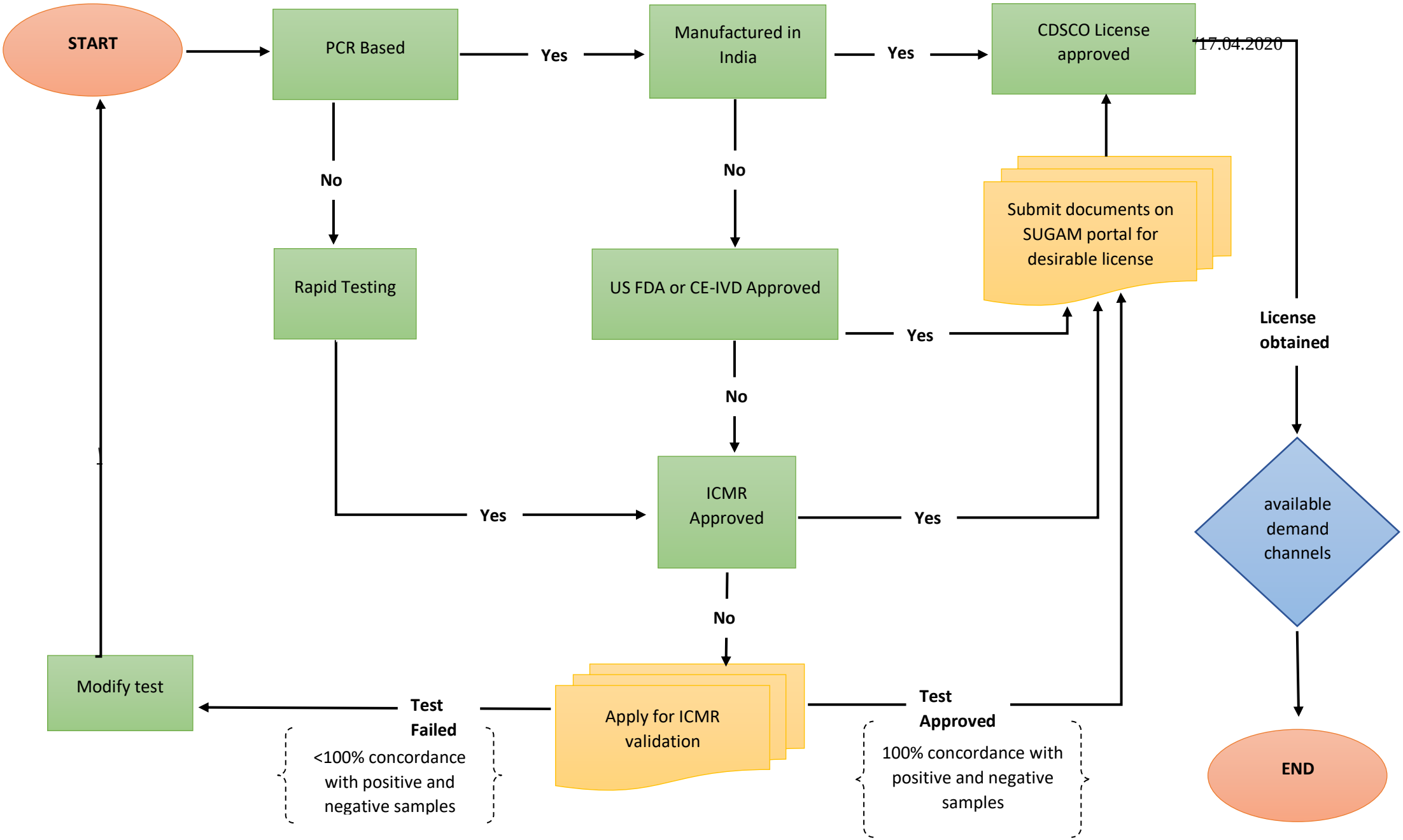
- User can apply for Form 8 for three cases i.e. **Fresh, Endorsement and Renewal.**
- Before applying for **Endorsement** or **Renewal case**, user must fill the previous import license details first in **Permission Owned/Historical** data menu.
- User should fill all the required (mandatory) fields to fill the form.
- After filling the form till first preview, user can modify the form.
- Once user moves to the checklist, user will not be able to modify the form. So, user should provide all correct entries.
- If user do not fill the complete application in one go, then application will be saved in **Saved As Draft mode.**
- To view application in, Saved **As Draft** mode, click on **Menu Form Submission Saved Applications**.

i) If user fill the complete application in one go, then application will be Submitted to CDSCO. To view Submitted Application, click on Menu Form Submission Submitted Applications.

j) If application is approved by CDSCO, then it will be visible under Approved Applications tab. To view Approved Application, click on Menu Form Submission Approved Applications.

k) If application is rejected by CDSCO, then it will be visible under Rejected Applications tab. To view Rejected Application, click on Menu Form Submission Rejected Applications.

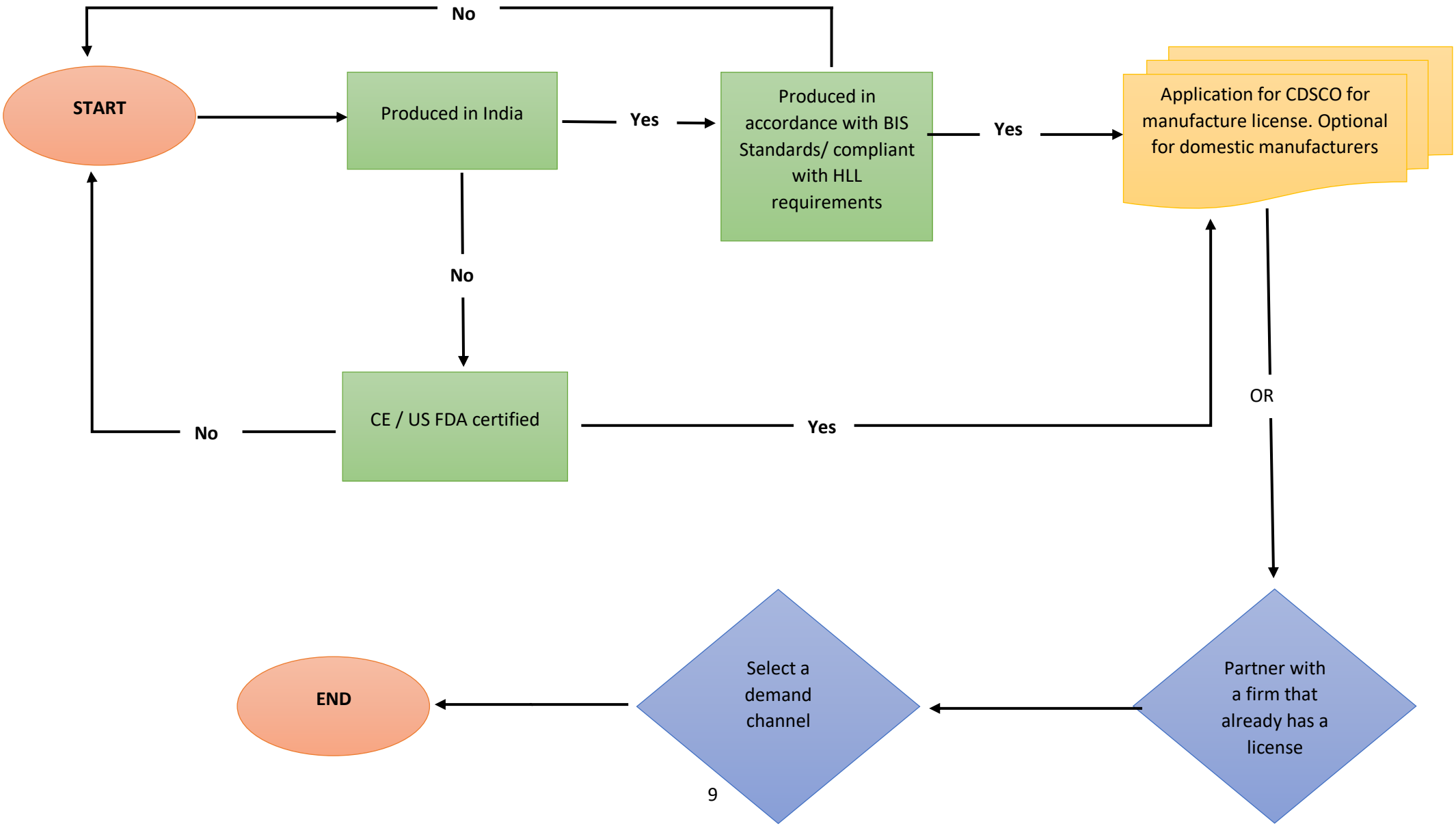
Covid Diagnostic Kits Approval Flow Chart (next page)


START
PCR Based
Yes
Manufactured in India
Yes
CDSCO License approved
17.04.2020
No
No
Submit documents on SUGAM portal for desirable license
Rapid Testing
US FDA or CE-IVD Approved
Yes
License obtained
No
ICMR Approved
Yes
Yes
available demand channels
No
Modify test
Test Failed
<100% concordance with positive and negative samples
Apply for ICMR validation
Test Approved
100% concordance with positive and negative samples
END

2) Ventilators

Substantive – specification and standards	Standards a) Certified for meeting IEC 60601-1-4 Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems. Essential to obtain within 30 days of placing the order. b) IS/ISO 80601-2-12: 2011 'Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators c) IS/ISO 10651-3: 1997 'Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators d) IS/ISO 10651-4: 2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators e) IS/ISO 10651-5: 2006 'Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators f) IS/ISO 10651-6: 2004 'Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support For ISO standard particulars, refer to: https://www.bsbedge.com/IndianStandardsonCovid19 HLL tender technical specifications may be found here: http://www.lifecarehll.com/tender
Approval Process	All approval process routed through CDSCO. Presently, in the interest if time the licensing from CDSCO is an optional one. User manual for filling out CDSCO form for medical devices: https://cdscomdonline.gov.in/NewMedDev/resources/app_srv/NMD/global/pdf/MD_User_Manual_Guidance.pdf
Source/ Regulating body	g) IEC standards h) CDSCO
Clarifications sought	Status of upcoming R&D, especially since CDSCO license is optional.

Ventilators Approval Flow Chart



3) PPE

Substantive – specification and standards[3]	Nitrile Gloves a) Nitrile b) Non-sterile c) Powder free: d) Outer gloves preferably reach mid-forearm (minimum 280 mm total length) e) Different sizes (6.5 &7) f) Quality compliant with the below standards, or equivalent: i. EU standard directive 93/42/EEC Class I, EN 455 ii. EU standard directive 89/686/EEC Category Ill, EN 374 iii. ANSI/SEA 105-2011 iv. ASTM D6319-10 Sterile Gloves a) Latex – IS 13422 with ISI mark b) Non-sterile (disposable) c) Latex – IS 4148 with ISI mark Examination Gloves a) Size: Medium and Large b) Powdered c) Latex – ASTM D-3578 PPE Coverall (medium and large)* a) Impermeable to blood and body fluids b) Single use

[3] http://www.lifecarehll.com/COVID_19_Product_Specification.pdf

	c) Avoid culturally unacceptable colours e.g. black d) Light colours are preferable to better detect possible contamination e) Thumb/finger loops to anchor sleeves in place f) Quality compliant with following standard i. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent ii. EN 14126 PP Coverall with tape over seam along with shoe cover a) Impermeable to blood and body fluids b) Single use c) Avoid culturally unacceptable colours e.g. black d) Light colours are preferable to better detect possible contamination e) The fabric, garment/coverall and seam should pass the Synthetic Blood Penetration Test at SITRA f) Coverall shall be designed to be universal fit g) Coverall should have built Hood Cap h) Zipper of the coverall shall be covered with a flap to avoid accumulation of microbes i) Soft elastic to be fitted around front of hood, wrists and ankles j) SITRA compliant Goggles a) With transparent glasses, zero power, well fitting, covered from all sides with elastic band/or adjustable holder. b) Good seal with the skin of the face c) Flexible frame to easily fit all face contours without too much pressure d) Covers the eyes and the surrounding areas and accommodates for prescription glasses e) Fog and scratch resistant f) Adjustable band to secure firmly so as not to become loose during clinical activity g) Indirect venting to reduce fogging h) May be re-usable (provided appropriate arrangements for decontamination are in i) place) or disposable

	j) Quality compliant with the below standards, or equivalent: i. EU standard directive 86/686/EEC, EN 166/2002 ii. ANSI/SEA Z87.1-2010 Boot Covers a) Made up of the same fabric as of coverall b) Should cover the entire shoe and reach above ankles c) Soft elastic to be fitted at two levels, ankle and end. Face Shield a) Made of clear plastic and provides good visibility to both the wearer and the patient b) Adjustable band to attach firmly around the head and fit snuggly against the forehead c) Fog resistant (preferable) d) Completely covers the sides and length of the face e) May be re-usable (made of material which can be cleaned and disinfected) or disposable f) Quality compliant with the below standards, or equivalent: i. EU standard directive 86/686/EEC, EN 166/2002 ii. ANSI/SEA Z87.1-2010 Body Bags-Specifications a) Impermeable b) Leak proof c) Air sealed d) Double sealed e) Disposable f) Opaque g) White h) U shape with Zip i) 4/6 grips

	j) Size: 2.2 x 1.2 Mts k) Standards: i. ISO 16602:2007 ii. ISO 16603:2004 iii. IS016604:2004 iv. ISO/DIS 22611:2003 N-95 Masks a) Shape that will not collapse easily b) High filtration efficiency c) Good breathability, with expiratory valve d) Quality compliant with standards for medical N95 respirator: i. NIOSH N95, EN 149FFP2, or equivalent ii. Or ISI specification e) Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent f) Quality compliant with standards for particulate respirator that can be worn with full- face shield g) Raw materials for the mask should be procured from certified vendors/suppliers/manufacturers with recognized certification (BIS, ISO). Triple Layer Medical Mask a) Three layered surgical masks of non-woven material with nose piece, having filter efficiency of 99% for 3micron particle size. b) ISO 13485/ ISO 9001/ EN 14683 or equivalent. Homemade Cotton Mask (not acceptable as part of the PPE kit and does not require any regulatory compliance; *see* manual below for best practices) Office of the Principal Scientific Advisor to the Government of India has issued a manual on homemade masks for curbing spread of SARS-CoV-2 Coronavirus

	http://164.100.117.97/WriteReadData/userfiles/FINAL%20MASK%20MANUAL.pdf Components of PPE: Googles, Face-shield, Mask, Gloves. Coverall/gowns, head cover and show cover. Note: all items are being procured directly by HLL and the changing specs are regularly updated on the HLL website
Approval Process	a) The compliance in standards for Synthetic Blood Penetration Resistance Test facilities will be checked at the Ministry of Textiles mandated laboratories. List of the 4 labs accredited: SITRA (South India Textile Research Association), Coimbatore, DRDE (Defence Research Development Establishment), Gwalior, Heavy Vehicles Factory, Tamil Nadu and Small Arms Factory, Kanpur.[4] To overcome delays, DRDO has shifted testing facility from DRDE, Gwalior to Institute of Nuclear Medicine & Allied Sciences (INMAS), Delhi. DRDE has been tasked with testing of masks received by HLL from foreign countries before further disbursement.[5] b) For each test conducted at SITRA for which proto-type samples sent by manufacturers, SITRA will generate a Unique Certification Code (UCC-Covid 19). This code shall keep a record of the type of fabric, type of garment, and its date of testing, testing standard, and other relevant particulars. The procedure for certification will be set up by SITRA. Similar procedure will be followed by DRDE. Corollary: applicable to the two labs added on 11th April 2020. c) The PPE Garment manufacturer will manufacture in accordance with the materials and workmanship as per the tested and certified proto-type sample. Any change shall require new certification and generation of a new Code. d) The PPE garment manufacturer will either print in indelible ink or stick a tamper-proof sticker, on the body of the garment with the following particulars: i. Name of manufacturer: ii. Approved lab UCC: iii. Test Standard: iv. Date of Manufacturing/ Batch Number: v. Order: HLL Life Care Limited if material is supplied to HLL. State Government and other bulk procurement agencies may insist o similar requirement if desired. Not mandatory for retail orders.

[4] http://texmin.nic.in/sites/default/files/QC_Addendum1.pdf.pdf
[5] https://pib.gov.in/PressReleseDetailm.aspx?PRID=1615019

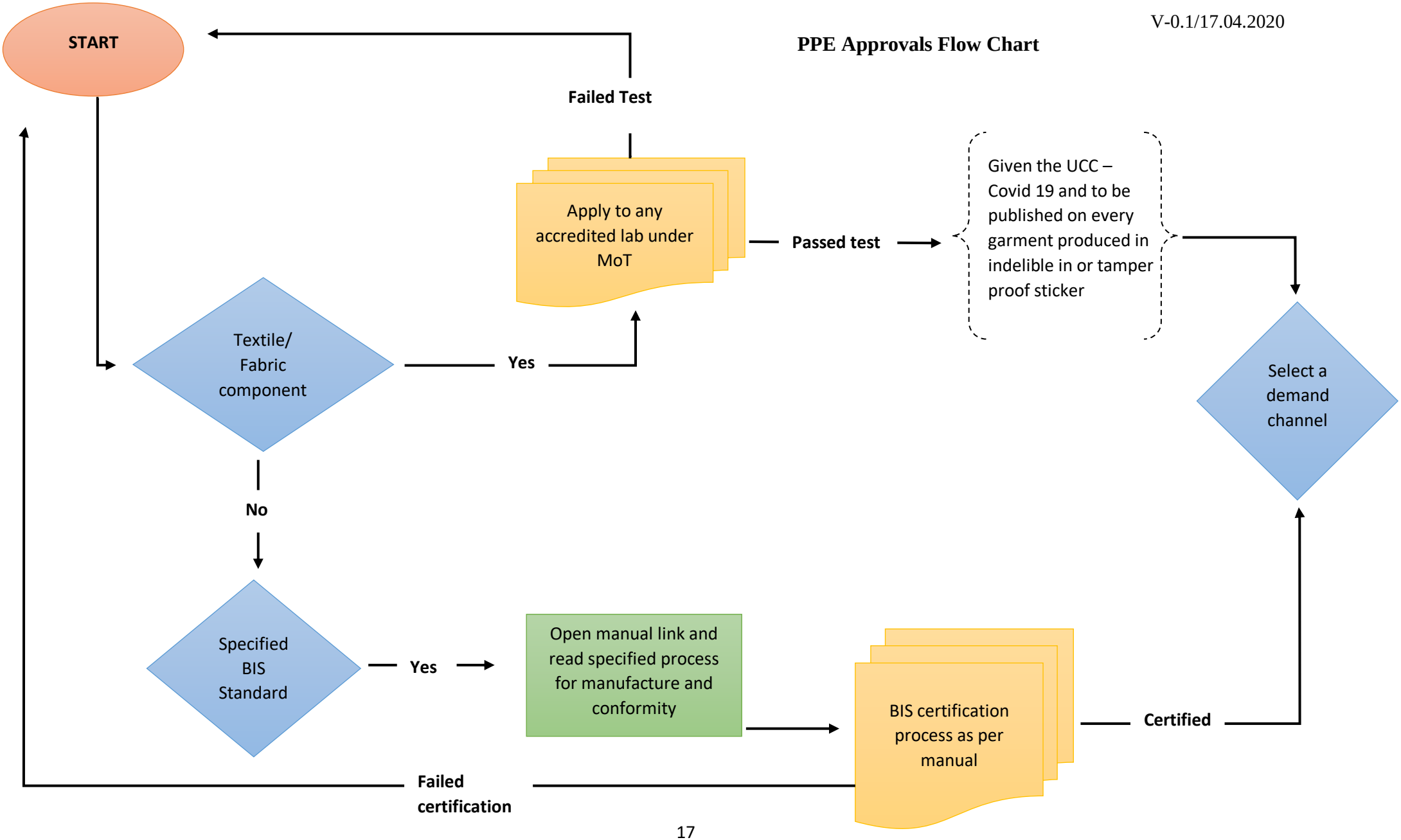
	e) HLL will devise a sampling plan with regard to the frequency of test sample collection from the lots which are supplied progressively by the Manufacturer. f) Due to scarcity of coveralls, as an emergency temporary measure in larger public interest, the fabric that cleared/ passed 'Synthetic Blood Penetration Resistance Test' (ISO 16603) and the garment that passed the 'Resistance to penetration by biologically contaminated solid particles (ISO 22612:2005) may be considered as the benchmark specification to manufacture Coveralls. The Coveralls shall be taped at the seams to prevent fluid/ droplets/ aerosol entry. [6] g) All testing is being done with WHO compliance standards. SITRA's testing document may be used for guidance of how to navigate testing: http://cliqinnovations.com/projects/sitra/wp-content/uploads/2020/04/CoE-for-Website.pdf h) The BIS has specified Standards for each of the medical supplies. Each device linked with a Standard has a separate compliance document of its own. These compliance documents may be accessed via this link: https://www.bsbedge.com/IndianStandardsonCovid19. The relevant document contains packing. Sampling, testing for conformity, usage of Standard Mark and the method of determination of compliance for each product separately.
Logistics/ Infrastructure[7]	a) BIS has a very specific procedure for allowing usage of the ISI mark or to certify compliance with the Standard set. b) The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. c) BIS operates a product certification scheme for ensuring compliance to Indian Standards. Presence of BIS standard mark (also known as ISI mark) on a product indicates conformity to the relevant Indian Standard. To cater to the needs of testing for certification activity, BIS has established eight labs in the country namely: Western Regional Office Laboratory (WROL), Mumbai; Northern Regional Office Laboratory (NROL), Mohali; Eastern Regional Office Laboratory (EROL), Kolkata; Southern Regional Office Laboratory (SROL), Chennai;

[6] https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf
[7] https://bis.gov.in/PDF/cart/BIS_Conformity_Assessment_Regulation_2018_Gazette_Notification.pdf

	Bangalore Branch Office Laboratory (BNBOL), Bangalore; Patna Branch Office Laboratory (PBOL), Patna; Guwahati Branch Office Laboratory (GBOL), Guwahati. a) BIS has also recognized NABL accredited labs and govt labs to discharge the work related to testing of products for conformity assessment and allows for self-regulation in the interest of efficiency. b) Testing and fee – BIS testing facility portal - http://164.100.105.198:8096/bis_access/iswise_v2.html . Type out the ISO number, the page redirects to testing labs and other facilities. For detailed guidelines on application process for management systems: https://bis.gov.in/wp-content/uploads/2018/10/Guidelines_for_applicants.pdf
Source/ Regulating body	a) Accredited labs under Ministry of Textiles[8] b) BIS for compliance with specified standards c) HLL Life Care for sampling, collection and acceptance procedure
Clarifications sought	No fast track mechanism to obtain BIS license / Standard Mark

[8] http://texmin.nic.in/sites/default/files/QC_Letter.pdf.pdf

PPE Approvals Flow Chart



4) Sanitizer

Substantive – specification and standards[9]	Hand sanitizers are licensed under Drugs and Cosmetics Rules, 1945 under the Second Schedule of Drugs and Cosmetics Act and rules made thereunder. https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/ On March 13, 2020, the central government had notified hand sanitizers under Essential Commodities Act, 1955 to regulate their production, quality, distribution and logistics. https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/Notification21mar2020.pdf On March 21, 2020, Government capped price of hand sanitizers https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/Notification21mar2020.pdf A number of measures taken to increase quantities of hand sanitizer produced[10]: a) Necessary permission on account of licensing and storage of Ethyl Alcohol/ extra neutral alcohol/ Ethanol may be accorded by the State Government agencies to the sanitizer industry up to installed capacity without any quota restriction on supply. b) Indian Sugar Mills Association and All India Distilleries Association have assured input material would be made available at a reasonable price. c) All permissions needed by the distilleries to be provided on a priority basis. As per the HLL tender document, the following options are available for production: a) 2 Propanol BP 45%. 1 Propanol BP 30% Macetronium ethyl sulphate 0.2%

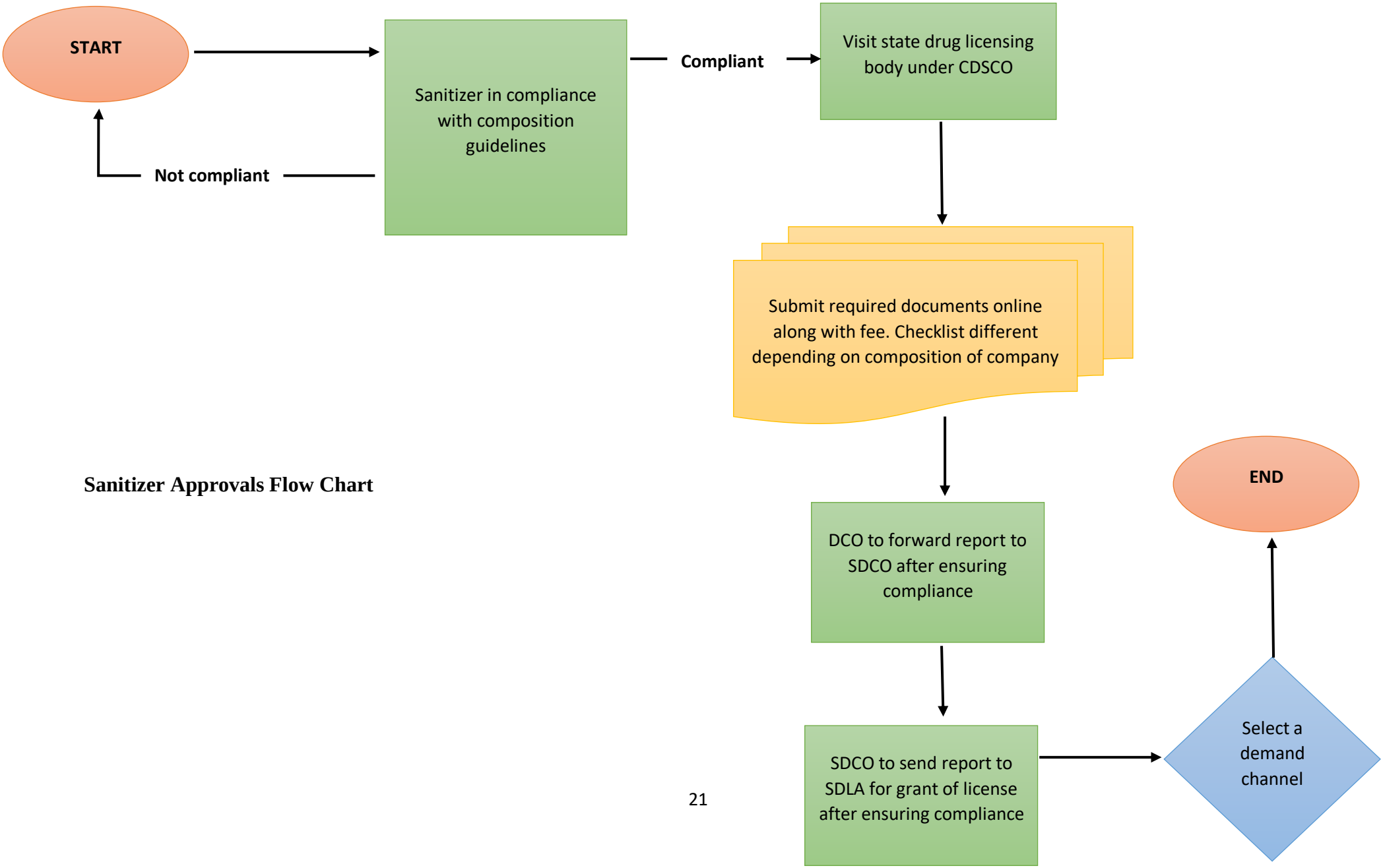
[9] https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf
[10] https://prsindia.org/files/covid19/notifications/99.IND_DFPD%20Letter%20to%20States%20to%20Permit%20Alcohol%20and%20Distilleries_March%2019.pdf

	a) Isopropyl alcohol IP (72% w/w) Quinolone yellow Triclosan .30% w/w Excitents-q.s b) Chlorhexidine Gluconate solution IP 2.5% v/v Ethyl Alcohol IP 70% v/v c) Glycine – 1% Aloe Vera Extract – 0.1% DM water – 25.56% Examples of CDSCO approved hand sanitizers - https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc4Mg==
Approval Process	Application for manufacture and sell is a subject matter of state. Each state has its own web portal/ physical process for application. Procedure to obtain Drug License (under CDSCO) is: **a) Signing up on Website:** Firstly, the applicants need to visit the website of their respective State Drug Licensing authority and register themselves by filling the registration purpose. After that, the applicant has to fill his details, organization details, and contact details to generate OTP. **b) Uploading documents:** After filling up the form, the applicant has to upload documents. The documents checklist is mentioned on the website depending upon the composition of the company. **c) Payment of Fees:** After uploading all the documents, requisite fees of the form should be submitting and generate challan of that for further processing. **d) Scrutinization of Documents:** After submitting the form, the licensing authority will scrutinize the form, and the DOC (District Coordination Officer) of the concerned district will inspect the organization and ensures that it comply with all the requirements. **e)** After the verification and inspection, the DCO will forward the report to the SDCO of the zone for granting the License. **f) Issuing Drug License:** The report of SDCO will be forwarded to the respective State Drug License Authority, and, if the authority finds no discrepancy in the report, then it will issue Drug License to that person.

	The State/ UT Drug Controllers have been directed to grant manufacturing license within three working days.[11]
Logistics/ Infrastructure[12]	Co-ordination officers: a) JS (Sugar, D/o Food and Public Distribution, and D/o Consumer Affairs to coordinate with Alcohol distilleries; Excise Commissioners and Drug Controllers in States to start manufacture through alcohol distilleries. b) Secretary, D/o Consumer Affairs and Js (sugar) to coordinate with states ensuring functioning of bottling plants. c) States to waive inspection for starting production. Post facto approval may be sought. Secretary, Pharmaceuticals to coordinate. Area for the operations of the business: A minimum area of 10 sq meters is required to set up a medical shop or retail pharmacy. If they are operating with a wholesale one, and then the minimum of 15 square meters is mandatory.
Source/ Regulating body	CDSCO and Respective State Government will issue this License according to their eligibility terms.

[11] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc4Ng==
[12] https://prsindia.org/files/covid19/notifications/149.IND_ethanol_production_March24.pdf
https://prsindia.org/files/covid19/notifications/149.IND_ethanol_production_March24.pdf

Sanitizer Approvals Flow Chart



II. Manufacturing *[TBD]*

III. Funding

1) *Low interest SIDBI loan if you are a profit-making company*

   a. **Context**: COVID-19 pandemic has impacted the entire economy and the startup ecosystem is no exception. SIDBI recognizes the operational and financial challenges being faced by the start-ups and endeavours to provide financial assistance and stability via its scheme viz. Covid-19 Startup Assistance Scheme ('CSAS'). This scheme will provide assistance to innovative startups that have demonstrated ability to adapt to economic impact from Covid-19 and ensured its employees safety and financial stability. SIDBI does not extend credit to startups and only specializes in equity and fund infusion, it is starting this Scheme in view of unprecedented situation and the consequential cash crunch faced by many startups. This is purely an interim arrangement.

   b. **Scheme and Process**: CSAS aims to provide assistance to startups that will directly benefit from the scheme. The objective of the Scheme is to provide quick working capital in the next 45 to 60 days to the Start-ups. Therefore, for a faster processing a Recommendation Committee comprising of 5 members (3 from SIDBI and its nominees and 2 from Venture Capital Industry) will be created. The process followed for screening by the application shall be as follows:

      i. The Scheme document shall be available on SIDBI portal.
      ii. An application cum Credit Appraisal Memo (CAM) along with Self-Assessment Tool (SAT) shall be made available on the SIDBI portal.
      iii. Start-ups are required to fill the CAM, SAT, and submit the documents to a designated email id (csas@sidbi.in), within 30 days of launch of the Scheme.
      iv. The Recommendation Committee will run a process, which will include a credit evaluation, Video Conference with the startup and VC Investor.
      v. Thereafter proposed Internal Credit committee of SIDBI (ICC) will hold a weekly meeting to approve loans to Startups. During the ICC meetings, the Startups along with the VC Investor may be required to be available for a Video Conference meeting.
      vi. Approval or rejection will be communicated on the same day by email.
      vii. The Loan Agreements and related documentation will be completely digital.

The Scheme will be launched all throughout the country, for Government defined Start-ups, based on the eligibility criteria detailed in the Scheme.

c. **The broad parameters of the Scheme are given below**:

Name of the Scheme	Covid-19 Startup Assistance Scheme (CSAS)
Type of Facility	WCTL
Purpose	To provide interim support to startups whose cash flow and liquidity has been adversely impacted by the Covid-19 pandemic. The assistance can be used for various working capital requirements like salaries / wages, rent, administrative expenses, payment to vendors etc. The loan may also be considered against the GST refund.
Tenor of the Loan	Up to 36 months including maximum moratorium period of 12 months. Loan to be repaid in max 24 instalments.
Loan Amount	Not more than INR 2 Crores per Start-up
Eligible Beneficiaries	Eligibility criteria for startups: *I.* Government defined Start-ups which has received funding through at least one of the Alternate Investment Funds registered with SEBI. *II.* Startups with a minimum employee base of 50 employees. This may also include the foot soldiers. (Relaxable on case to case basis). *III.* Startups having FY 2019 and FY 2020 minimum turnover between INR 10 crore to INR 60 crore. *IV.* Startups should have positive unit economics. *V.* Startup should have been incorporated for less than 10 years. *VI.* Startups should have a positive Net Worth. *VII.* Startups should have demonstrated innovative measures for ensuring business continuity during the Covid – 19 period. *VIII.* Startups should have taken adequate measures and ensured employee safety and their financial stability. *IX.* Promoter / Founder of startup should have invested his own capital in the business The below category is not eligible *I.* Written off Startups by AIFs. *II.* Startups who are in Stress usually other than the present Covid-19 (as recommended by the Fund Manager).

	III. Startups having working capital facilities with any Bank.
Insurance for Employees	Each loan to the Start-ups will carry the following Insurance. *I.* Key Man insurance assigned to SIDBI. *II.* All employee term Insurance up to 10 lakhs. Cost of premium shall be borne in following pattern: • 50% by SIDBI • 25% by the Investor Fund 25% by the Startup The share of startup may be apportioned in the loan disbursement amount.
Margin/Promoters Contribution	NIL
Rating	Not Applicable
Security	<u>Mandatory Security:</u> • First Pari-Passu charge on current assets of the Company • Keyman Insurance to the extent of facility amount disbursed to secure the facility. <u>Additional Security, if available:</u> • Hypothecation of movables of the company. • Pledge of Intellectual Property • Pledge of Promoter shares
Interest rate	10.50% p.a. reducing balance
Disbursement Mechanism	Need based single / multiple tranche
Share Warrant Option	At any time, during the currency of the WCTL, SIDBI will have the right to subscribe up to 10% of the Loan Amount with 50% discount to previous tranche.
Processing Charges	1% of the sanction amount
Prepayment Charges	Nil
Conversion in case of Default	In case of default in repayment / payment of principal or interest instalment(s) continuing for more than 180 days, then SIDBI will have the right to convert that defaulted instalment(s) along with its accrued interests,

	penal interests and all other costs and charges (either in full or in part) into equity capital of the Company "at par".
Other Conditions	I. The assistance cannot be used to pay any debt including Venture Debt. II. It will not be subordinate debt. III. The promoter or investor cannot sell shares without SIDBI's consent.
Legal Documentation	As per the facility and security provided
Recommendation Committee	Recommendation Committee to be set up by SIDBI.
Sanctioning Authority	Internal Credit Committee to be set up by SIDBI.
Source of Fund	SIDBI's Balance Sheet as SIDBI will directly provide the facility to start-up.