Challenges of meeting standards and conformity assessment in the times of Covid – Indian industry experience

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Anupam Kaul
Principal & Head (Quality, Metrology & Standards)
CII Institute of Quality

Confederation of Indian Industry

INSTITUTE of QUALITY

India Covid situation

Despite one of the longest lockdown (25 March to 31 May), the Covid curve has not flattened, and the Government had to get into unlock phase. Several restrictions are still in place with access control in containment zones and ban on social gatherings

India Covid situation

- Even though the extended lockdown could not achieve halting the spread due to multiple social constraints, a large migrant population, it has given the Government time to prepare the response infrastructure to deal with the numbers.
- Besides augmenting healthcare infrastructure for Covid related patients, this includes development of a supplier base for Covid testing kits, as well as PPEs and medical devices such as ventilators

Technical Regulations

India notified the Medical Devices Rules, 2017 under the Drugs and Cosmetics Act aligned with GHTF risk classification

Product standards for medical devices conformance:

- The standards laid down by the Bureau of Indian Standards established under the Bureau of Indian Standards Act, or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.
- Where no relevant Standard of any medical device has been laid down under sub-rule, to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.
- In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), to the validated manufacturer's standards.

List of currently regulated Medical Devices

1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	Substances used for in vitro diagnosis including Blood Grouping Sera
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices
16.	Ligatures, Sutures and Staplers
17.	Intra Uterine Devices (Cu-T)
18.	Condoms
19.	Tubal Rings
20.	Surgical Dressings
21.	Umbilical tapes
22.	Blood/Blood Component Bags
23.	Organ Preservative Solution*

List of Medical Devices to be regulated from future date

24.	Nebulizer (effective from 1 Jan.2021)
25.	Blood Pressure Monitoring Device(effective from 1 Jan.2021)
26.	Glucometer (effective from 1 Jan.2021)
27.	Digital Thermometer (effective from 1 Jan.2021)
28.	All implantable medical devices Equipment (effective from 1, April,2021)
29.	CT Scan Equipment (effective from 1, April,2021)
30.	MRI Equipment (effective from 1, April,2021)
31.	Defibrillators (effective from 1, April,2021)
32.	PET Equipment(effective from 1, April,2021)
33.	X-Ray Machine (effective from 1, April,2021)
34.	Dialysis Machine (effective from 1, April,2021)
35.	Bone marrow cell separator (effective from 1, April,2021)
36.	Disinfectants and insecticide specified in Medical Devices Rules, 2017
37.	Ultrasound equipment (effective from 1, November, 2020)

Class C & D Devices shall be evaluated by the Regulator

Class A & B Devices can be evaluated by Notified Bodies in India or overseas

Registration of Medical Devices

- From 1st April 2020, the Ministry of Health & Family Welfare has notified registration of all medical devices (excluding those covered under mandatory compliance)
- The registration is based on conformance to ISO 13485 issued by CBs accredited by NABCB (India) or bodies under IAF
- The registration will be voluntary till 30th September 2021, after which it will be mandatory
- An advisory has been issued for PPE suppliers to voluntarily register themselves

Covid testing kits

PCR Kits suppliers approved for testing of Covid-19 as on 05.06.2020 by CDSCO

- Total 105 suppliers : Indigenous 12, Imported 93

Rapid / CLIA/ ELISA Kits approved for testing of Covid-19 (Antibody test IgG/IgM, Fluorescent Rapid ANTIGEN Test , ELISA, CLIA, Standard Q COVID-19 IgG/IgM Combo etc

- Total 108: Indigenous 13, Imported 95

VALIDATION for RT-PCR Kits, RNA Extraction and VTM Kits, Rapid Antibody Test; ELISA and CLIA Kits

- US-FDA approved kits will not require validation.
- CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: Kits will require validation from any of ICMR identified validation centres
- Batch testing certificate will be required while delivering the consignment.
- ICMR identified validation centre will undertake random samples testing of batches of kits for quality assurance
- 24 Validation Centres have been notified

Proactive steps by Regulator

- The Regulator for drugs and medical devices, CDSCO adopted the regulatory reliance model and revised the regulatory process in such a way that the approvals for the Covid related products were issued in less than seven days to all manufacturers.
- CDSCO also issued many concessions in the submission of documents like legalized Power of Attorney, Notarization of regulatory process etc so that the business continuity could be maintained
- Even the normal approvals and renewals for medical devices are being issued in less than 20 days which is a significant improvement in the regulatory approval process.
- At the same time, regulatory decisions like cancellation of licences, were taken to ensure that only quality medical devices and IVDs are distributed in the country.

Standards / quality requirements for PPE

The ministry of Health have issued guidelines for rational use of PPEs

Provides guidance for the specific PPEs to be worn by personnel in different settings and tasks performed such as :

- Airports (Ports) – Health-desks, immigration counters, Isolation facility, sanitary staff
- Hospitals – Out Patient setting – Triage area (Patients, visitors) Help desks, holding area, doctors chambers etc
- Hospitals – In Patient setting – individual / isolation wards, ICU /Critical care, Non Covid areas, sanitation staff,
- Emergency station, Ambulance, supportive / ancillary services
- Health Workers in Community settings
- Quarantine facility
- Home quarantine

PPEs covered

- Coverall/gowns (with or without aprons),
- Masks (N95 and Triple layer)
- Goggles,
- Face-shields
- Gloves,
- Head cover
- Shoe covers

Standards / quality requirements for PPE

The Guidelines provide qualitative aspects for all products and specifications/ standards

- Gloves - EU standard directive 93/42/EEC Class I, EN 455 ; EU standard directive 89/686/EEC Category Ill, EN 374 ; ANSI/SEA 105-2011 ; ASTM D6319-10
- Coverall (medium and large) - Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent
- Goggles - a. EU standard directive 86/686/EEC, EN 166/2002 b. ANSI/SEA Z87.1-2010
- N-95 Masks - NIOSH N95, EN 149 FFP2, or equivalent, Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609
- Face Shield - EU standard directive 86/686/EEC, EN 166/2002; ANSI/SEA Z87.1-2010
- Triple Layer Medical Mask – Indian Standard (IS 16289 - Surgical masks, IS 14166 : 1994 full face masks)

Coveralls:
Due to lack of industry preparedness, currently only the Blood permeability test with viral load (Class 3) test and seam joints are being tested for type approval

Bureau of Indian Standards is currently in the process of developing a simplified standard for Coverall for specific Covid related uses

All items to be supplied need to be accompanied with certificate of analysis from national/ international organizations/labs indicating conformity to standards

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Certification of Coveralls

- Coveralls were not being manufactured in India.
- Under a special initiative by Ministry of Health & Family Welfare and Ministry of Textiles, Industry was invited to take up their production
- As India has a large base of textile product producers, many came forward to take up their production. As of now an estimated 700 manufacturers have registered their samples
- The current production level is approx. 300 000 pieces per day
- The expected demand is more than 30 million pieces as per current estimates
- The ministry of Textiles has designated 9 laboratories to conduct the permeability and seam test and appointed accredited third party inspection bodies for lot inspections
- Currently no imports or exports are happening for Coveralls

Coverall type certification

THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION
CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES
Physical, Chemical & Biological Testing Laboratories
(ISO/IEC 17025 NABL ACCREDITED)
13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA
TC-6944

UNIQUE CERTIFICATE CODE (UCC)
For Personal Protection Equipment (PPE) Body Coverall for COVID -19

This Certificate Code is issued to

M/s Alok Industries Limited

with registered address as,
374/2/2,,, VILLAGE SAILY, SILVASSA
Silvassa, Dadra And Nagar Haveli, Pincode : 396230,
Contact No(s) : 0260-6637500
Email : info@alokind.com

against their **Coverall Body Suit test sample** with Sample No. **P2000197** submitted to us on 10-04-2020 12:15:17 PM and tested on 13-04-2020 09:15:42 AM. The sample has **passed** the **Synthetic Blood Penetration Test** conducted as per **ASTM F 1670/F 1670M-08(2014)**, and conforms to the technical requirement of Ministry of Health & Family Welfare guidelines dated 02.03.2020. The test results are annexed to this certificate at page Nos. 2 to 3.

The sample's UCC code is:

S-NW-CA200410P0197-A3B1

which is valid upto 13-10-2020.

The affidavit furnished by the applicant in relation to their sample is annexed alongwith as Annexure 2 to this certificate.

This Certificate is based on the sample submitted by the applicant. No other test/verification has been conducted by SITRA other than results in the test report. The procurement agency is advised to conduct prior, due diligence as per their procurement policy, including periodical sample tests during the course of supply of the materials.

-sd-

Authorised Signatory

THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION
CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES
Physical, Chemical & Biological Testing Laboratories
(ISO/IEC 17025 NABL ACCREDITED)
13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA
TC-6944

Alok Industries Limited, Ref : Dt.07.04.2020 **ULR: TC694420600000354F**

(Sample Tested at : R.H.65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Synthetic Blood Penetration Test *ASTM F 1670/F 1670M-08(2014)*	**P2000197-1** Described by the Customer : **Suit with DRDO Glue Item Number PA - X2 - PP Suit - Pioneer Fabric - PA - 52 GSM**
Result at Fabric Portion	Pass
Result at Seam Portion	Pass

Note: COVID 19 Warning - The above report pertains only to the sample submitted by the customer and the samples are not drawn by SITRA. These results need not be indicative of the results of bulk lots of the articles under consideration. The onus of maintaining the Traceability between the sample submitted for testing and the bulk lot supplied lies with the customer / supplier. Samples may be drawn from the bulk lots by neutral organisations and the same shall be tested to ensure their compliance with the respective quality requirements.

- End of Report -

Steps by CII

- CII is India's largest and most active industry body that works closely with the Government. Besides advocating industry interests, CII pursues a holistic social agenda to promote equitable
- Formed a coalition for augmenting the inventory of Ventilators and Personal Protection Equipment (PPE) through manufacturing and/or importing of the same by the non-healthcare companies
- Reached out to various Member private hospitals on the various Essential Items for Critical Care requirements - and is currently collating this demand, which will be shared with relevant manufacturers both in India as well as abroad.
- Collated a list of the essential Items that will be required along with manufacturer details with the objective to facilitate a direct connect between buyer-manufacturers of these critical items for quick procurement
- Made policy suggestions for setting up the testing and inspection protocols for PPEs
- Live projections on both the demand and supply side can be viewed on the CII Covid Website. [https://www.ciicovid19update.in/]

Confederation of Indian Industry

125 Years: 1895-2020

COVID - 19 Interventions.

Show me list of Suppliers of Critical Items

Show me the Demand for Critical Items

Manufacturers & Suppliers of Critical Care Items

- Healthcare Facilities
- ICUs
- Quarantine Facilities

HEALTH CARE FACILITIES

HOSPITAL FURNITURE

Sl No	Company Name	CEO Name	Contact Person	E-mail id	Address	City
1	Godrej Interio	Anil Sain Mathur	Rajiv Khanna	khanna@godrej.com	Godrej Interio, Plant 13 Annexe, Vikhroli west, LBS Marg, Mumbai-400079	Mumbai
2	Stryker India Pvt Ltd	Shivkumar Hurdale (Director – GA/RA/QA India and ASPAC)		Shivkumar.hurdale@stryker.com	Vatika Business Park, 10th Floor, Block Two, Sector 49, Sohna Road, Gurgaon 122001, Haryana	Gurugram

Disposable OT/ICU patient gowns (Manufacturers)

Sl No	Company Name	CEO Name	Contact Person	E-mail id	Address	City
1	HEFEI C&P NONWOVEN PRODUCTS CO., LTD			info@cpnonwoven.com.cn		
2	Sara Healthcare P Ltd			info@sarahealthcare.com		
3	Z Plus Surgical gowns	Ravindra Radadiya		zplusdisposable@gmail.com		

Demand for Critical Care Requirement for COVID- 19 Pandemic Preparedness

Name of Hospital	SPOC	Email	Masks (N95)	3-PLY MASK	Gloves	PPE (full suit)	Sanitisers	Ventilator
Army Hospital	B. Brig Punit Yada	dirbudstd.21@gov.in	1370000	1760000	3000000	184000	219000 (Hand Sanitizer) 219000 -	3000
Dr. N. K. Aggarwal	Dr. N. K. Aggarw	nkaggrwl@hotmail.com		250	50	35	10	Nil
Aarogyam Hospital	Details not Given	sales.arogyam@gmail.com		5500	10000	300	5000	10
AASTHA HOSPITAL, Ank	Dr.Narendra Bara	aasthahospital.icu@gmail.com		50	50	5	10	Nil
Abhinav Nursing Home	Dr. Aparna Chinta	Charinakka@gmail.com	50			20		

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Demand Projection

(Amount in Thousands)

Masks (N95)	3-PLY MASK	Gloves
1561131	6029817	29363858

PPE (full suit)	Sanitisers (Ltr)	Ventilators
738350	935544	4330

More Details

Suppliers Identified

Masks (N95)	3-PLY MASK	Gloves
27	21	13

PPE (full suit)	Sanitisers	Ventilators
39	31	58

More Details

COVID - 19 Interventions.

CII COVID – 19 Helpline

Businesses across India are facing huge challenges due to the nationwide lockdown which is essential to contain the pandemic. CII provides real-time assistance for specific issues relating to essential supplies, clearances, movement of essential items, and so on. (Click here for the CII Helpline)

Global Advisories

Countries across the world are grappling with containing the spread of Coronavirus through various measures such as travel restrictions, lockdowns, and health advisories. They are also bringing out economic policies to assist in tiding over the crisis situations. CII captures these advisories and the latest developments on the policy front in the world which will enable businesses to judge the impact on their operations. (Read more)

Concerns

- The ISO / IEC standards for ventilators currently available are too prescriptive and entail a cumbersome type testing protocol. Some countries have come up with simplified Covid specific standards that include basic safety and minimum performance standards. It is necessary that a uniform standard is developed for assisting development and production of ventilators
- There are several reports of fake CE and FDA certificates being issued by non-accredited, unscrupulous certification bodies. All procurement agencies do not have the knowledge to distinguish between fake and original certificates. It is important that due awareness is created among agencies and users
- Multiple ministries and agencies often issue conflicting requirements that presents difficulties to industry in compliance. Governments need to create more synergy and coordination among agencies to preclude such instances

- Thank you