



ISO  
9001

**SEPTEMBER  
2020 ISSUE**



**Dr. Sundar Kataria**  
Chairman & Managing Director  
International Certification Services Pvt. Ltd.

## LIFE IS WAVE like Sinusoidal Curve

Corona-19 Pandemic has created a big wave in the world affecting Human and National Wellness, causing big impact on the National and International Economy. However life moves like sinusoidal curve. We can see a silver lining in the sky that will help us to revive the economy and enhance our GDP.

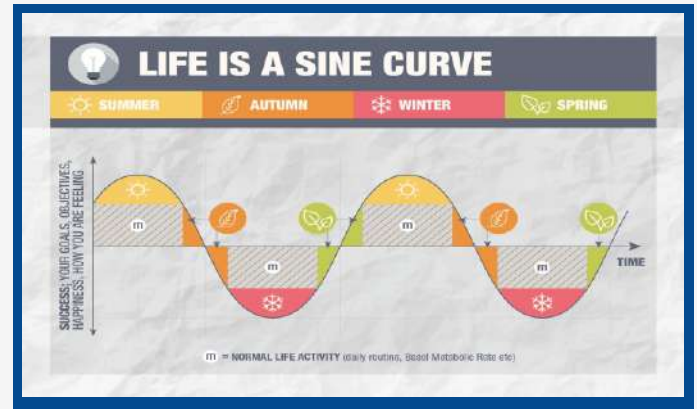
## What is most important in life?

It is growth and development GDP (Gross Domestic Product) or GNH (Gross National Happiness)? Today we are all confined and quarantined in home but the Life continues and sustains. We have aligned ourselves to new environment by continuing our work remotely using ICT; Information Communication Technology that is found to be more effective and efficient; moreover it is eco-friendly system.

We also have bigger challenges to provide work to our team that is difficult due to external forces as most of the project and site workers have been suspended temporarily, further more the manufacturing and service industries have shut down for past six months which are being "Revive" and started work partially. It may take another 4-6 months to go on full production.

## HOWEVER ABOVE CHALLENGES BRING MANY MORE OPPORTUNITIES.

We see big opportunities for India because of Government's new policies and guideline like "Aatma Nirbhar Bharat", support to MSME, development of cottage industry in Rural Areas including large Import substitution market.



## What is important for ICS to focus on:

Top quality, Ethical Practices, Independent and transparent, On-time delivery (JIT), value addition, compliance to legal and regulatory requirements health and safety, larger interest of All Stakeholders, social responsibilities, knowledge bank, use of latest technologies, and enhance trust among stake holders.

ICS has been providing certification of the management system and third party assessment with number of other related services. We at ICS are committed to build the Nation focusing and providing “Total Quality Management System” through.

- Corporate responsibility and governance
- Competitive and attractive fees structure
- Diversity – align with National Requirements, objectives and guidance.
- Quality through accreditation.
- Provide employment opportunity
- Adopt new technologies and systems
- Knowledge management edge over others
- Provide skilled manpower and talent managers
- Community benefits – social services
- Provide right and competitive environment
- Take organization forward
- Enter into digital world
- Leadership

International Certification Services is a provider of Products Certification of Medical Devices, Electrical, Mechanical and Electronic Equipment's, Machinery, Toys and Construction Products Materials etc. including CE Mark. There are over 20 pieces of CE marking legislations (Directives & Regulations) and one and more directives applies to your product, then it is mandatory to have CE mark for the European Union.

India has also adopted CE Marking apart from BIS certified IS: Indian Standard Mark. Whereas the Medical Devices falls under ICMED that has been made mandatory for all medical products, instruments and medical appliances so as to enhance the quality of medical devices to ensure its safe use.

ICS will provide you the certification of product services under single umbrella that will include certification, auditing and inspection and testing in their laboratory. We have two decade of experience for the certification and out services are accredited and well recognized in India and abroad.

The main objective of the IC-Med and EU directives is to regulate the products that are safe and complied with the applicable EU directives requirements and harmonized National and International Standards.

The manufacturer is responsible for the design, manufacturing, distribution and installation of the products by application of Good Engineering Practices and GMP etc. They also have to ensure the quality and consistency of the product through quality management system e.g.

- **ISO 9001: Quality Management System**
- **ISO 13485: Medical Devices Management System**
- **Certification by Third Party – Accredited Certification Body**
- **Inspection & Testing – Notified / Accredited Laboratory.**

The manufacturer or their authorized representative in the European Union, should declare compliance of the products to the requirements of the applicable directives before placing the CE mark by taking legal responsibility. There are some mandatory documents like TCF “Technical Construction File” and COD “Conformance of Declaration” including independent inspection and testing.



There are various approach for the Product certification. The manufacturer needs to take following steps and activities so as to obtain Certification of their product systematically:

<b>PRODUCTS:</b>	Product intended for use. Technical Specification Scope of the certification
<b>APPLICATION:</b>	Application to the certification body for registration
<b>APPROACH:</b>	Selection o right approach
<b>DOCUMENTATION:</b>	
<b>GENERAL:</b>	Technical Specification Process / Activities diagram Technical specification Drawings and BOM User guide – restriction of user Applicable Directives Harmonized Standards

#### TECHNICAL CONSTRUCTION FILE:

- Product/CE Documentation to cover all the necessary clauses of the applicable directives
- General – Product, scope and objectives
- Profile of the manufacturers and authorized representative and the responsibilities.
- Product conformity
- Internal Production control – quality management system.
- Inspection and testing – Independent testing laboratory (accredited)
- Technical construction file
- Declaration of conformity
- User manual
- Identification and labeling
- Distribution and packaging

**Most of the EU directives have undergone revision including new guidelines brought recently; the :**

1. The manufacturer shall ensure that their product have been designed and manufactured in accordance with the essential requirements.
2. The manufacturer and authorized representative assure their for the EU legal and regulatory requirements.
3. The product is certified by an independent CAB: Conformity Assessment Body and / or notified body.
4. All members of European Union are following “Union Safeguard Procedure” to ensure that products safety those are places in European Union. They also ensure the non-compliant apparatus / products are withdrawn from the Market. The manufacturer to co-operate and provide with all necessary information and data their product including re-dressal of the complaints.
5. Independent assessment by the “Conformity Assessment Bodies” to provide confidence through certification that product complied with necessary essential requirements and directive and design and manufacturer in accordance with the applicable harmonized standards.
6. DOC should specify the name of the conformity Assessment Body.

Please contact us for your valuable requirements. You may visit our website at [www.icspl.org](http://www.icspl.org) for further information and may call us for discussions.



**Dilip Negi**  
General Manager  
Manager (Admin/HR)



## ISO Certification at High Risk

Due to current COVID pandemic, ISO management system certifications at many companies are now at higher risk as conducting of onsite audits at client premises may not be permissible at many companies.

ISO standard 17021 states that if recertification assessment cannot be undertaken within six months [i.e. completing the auditing and the review process] the certificate shall be suspended and a new initial assessment will be required.



Worldwide numbers of certifications are at high risk of lapsing due to surveillance audits not being conducted in time.

This will lead to financial loss to many organizations, as it will considerably increase the levels of time and resources. Under such circumstance this will lead to most of the organizations to decide not to be re-audited and simply let their ISO certification lapse. This may lead to an unwanted decline in standards for the likes of information security, environmental management, health and safety and quality management.

Directly and indirectly this is not good outcome for anyone, be it organizations certified for ISO management system or Certification bodies that will lose their clientele.



**Jarna S Mandhyan**  
Senior Office Executive

## WHY ISO 22000 ?

ISO 22000 sets out the requirements for a food safety management system and can be certified to it. It maps out what an organization needs to do to demonstrate its ability to control food safety hazards in order to ensure that food is safe. It can be used by any organization regardless of its size or position in the food chain

## Who is ISO 22000 for ?

ISO 22000 is applicable to all organizations in the food and feed industries, regardless of size or sector. Following the same High-Level Structure (HLS) as other ISO management system standards, such as ISO 9001 (quality management), it is designed in a way that it can be integrated into an organization's existing management processes but can also be used alone.

## What are the benefits for my business ?

ISO 22000 enables organizations to put in place a food safety management system that helps them improve their overall performance when it comes to food safety. Key potential benefits of using the standard include:

- The ability to consistently provide food-related products and services that are safe and meet regulatory requirements
- Improved management of risks in food safety processes
- Demonstrating strong links to the United Nations' Codex Alimentarius, which develops food safety guidelines for governments

## Why was it revised ?

All ISO standards are reviewed and revised regularly to make sure they remain relevant to the marketplace. ISO 22000:2018 encompasses the latest trends and food safety requirements, and is a timely response to the rising global challenges facing the food industry. It will also help address the growing need to ensure we can trust current food security systems and that they are sustainable. ISO 22000:2018 includes improvements to definitions, including those that align with Codex Alimentarius. It also provides a new understanding of the concept of risk, distinguishing between risk at the operational level and the strategic level of a management system.







**V. Muralidhar**  
Vice President  
(Business Continuity)



## ISO 22000:2018 – FOOD SAFETY MANAGEMENT SYSTEMS

### Key changes in ISO 22000:2018

ISO 22000:2018 was released on June 19 2018, and is an international standard. As it follows the same High Level Structure (Annex SL) structure as other widely applied ISO standards, such as ISO 9001 and ISO 14001, it will be easier to integrate with other management systems.

#### Key changes in ISO 22000:2018

These are some of the key changes to consider:

#### 1) Changes due to the adoption of HLS

- Business Context and interested parties: Chapter 4.1, external and internal issues, introduces new clauses for systematic determination and monitoring of the business context, and Chapter 4.2, needs and expectations of interested parties, introduces demands to identify and understand factors that can (potentially) affect the ability of Management System to reach the intended results.
- Strengthened emphasis on leadership and management commitment: Chapter 5.1 now includes new demands to actively engage and take accountability for the effectiveness of the management system.
- Risk management: - Chapter 6.1 now requires companies to determine, consider and, where necessary, take action to address any risks that may impact (either positively or negatively) the ability of the management system to deliver its intended results.
- Strengthened focus on objectives as drivers for improvements: these changes can be found in Chapter 6.2, and performance evaluation chapter 9.1.
- Extended requirements related to communications: Chapter 7.4 is now more prescriptive in respect to the “mechanics” of communication, including determination of what, when and how to communicate.
- Less strict requirements for a food safety manual: – the change is introduced in chapter 7.5. It is still required to have documented information. Documented information shall be controlled to ensure it is adequately protected (ref. 7.5.3). The explicit requirement to have a documented procedure has been removed.

### Key Changes to ISO 22000:2018



#### High Level Structure

The new version of ISO 22000 will follow the same structure as all the other ISO management system standards.



#### Risk-based Approach

The new standard will now include a different approach to understanding risk.



#### Plan-Do-Check-Act (PDCA) Cycle

The standard clarifies the PDCA cycle, by having two separate cycles in the standard working together: one covering the management system and the other, covering the principles of HACCP.



#### The Operation Process

A clear description is given of the differences between key terms such as: Critical Control Points (CCPs), Operational Prerequisite Programs (OPRPs) and Prerequisite Programs (PRPs).

## 2) Other changes that are specific to ISO 22000 and food safety management:-

- The PDCA cycle: the standard clarifies the Plan-Do-Check-Act cycle, by having two separate cycles in the standard working together: one covering the management system and the other, covering the principles of HACCP.
- The scope now specifically includes animal food: food for animals not producing food for human consumption. Feed is intended to be fed to food producing animals.
- Some important changes in the definitions: 'Harm' is replaced by 'adverse health effect' to ensure consistency with definition of food safety hazard. The use of 'assurance' highlights the relationship between the consumer and the food product, based on the assurance of food safety.
- Communicating the food safety policy - Chapter 5.2.2: Explicitly requires the management to facilitate understanding of the food safety policies by employees.
- Food Safety Management System Objectives: Establishing objectives for the food safety management system is further specified in Chapter 6.2.1 and includes items as e.g. 'consistent with customer requirements', 'monitored' and 'verified'.
- Control of externally-provided processes, products or services - Chapter 7.1.6: This clause introduces the need to control the suppliers of products, processes and services (including outsourced processes) and to ensure adequate communication of relevant requirements, to meet the food safety management system requirements.

## Transition to ISO 22000:2018

### Recommended steps for the transition:

- Get to know the content and requirements of ISO 22000:2018. The standard is available for purchase from ISO and possibly from your national standards provider. If you are a current user of ISO 22000:2005 you should focus on the changes in requirements.
- Ensure that relevant personnel in your organization is trained and understand the requirements and key changes.
- Identify gaps which need to be addressed to meet the new requirements and establish an implementation plan. Implement actions and update your management system to meet the new requirements.
- Evaluate the effectiveness of implementation through internal audits and define further actions where needed.





**Rahul Kadam**  
Dy. Manager - HR

## Ganesh Festival Celebration 2020.

Ganesh Chaturthi, the birthday of the beloved elephant-headed Lord Ganesha,

also called Vinayak Chaturthi, is an auspicious Hindu festival which is celebrated for 11 days every year in the Bhadra month as per the Hindu calendar which generally falls in mid-August to September

Ganesh Chaturthi is by far the biggest community festival of Maharashtra. People of different cultures and different states usually visit city of Mumbai and other cities in the state to catch glimpses of the captivating Ganesha Idols.

However, Ganesh Chaturthi of 2020 was different due to the coronavirus pandemic that has brought routine life to a standstill across the globe. And hence, to stop the spread of the disease, Ganesh utsav organisers in the state have called off large scale celebrations. Hence, International Certification Services which is always working towards the welfare of the society decided to stand together in the Pandemic situation & celebrate this year Ganesh Festival by adhering the guidelines from the respective govt. and ensured there should not be any risk of close contacts and overcrowding.

ICS Ganesh Festival Committee under the guidance of Mr.Sumeet Kataria (Country Manager, ICS) played an important role by Organizing LIVE streaming of the Aartis and online Team activities for the devotees (ICS Asian Family), so that they can take part on a wide virtual platform.

Hence, we ICS family followed social distancing and hygiene rules while using the Virtual facility and took all the necessary quarantine precautions during this years Celebration. Also in such situation ICS HO had given positively equal opportunity to all our employees from our branches/Stations and group Companies (Pan India) to participate in this virtual Ganesh festival celebration.

In these 11 days of celebration we had fun full of enthusiasm, positive energy, feeling of togetherness even at the time when we are at our own home/places, under quarantine situation. And we have taken as opportunity which helped us to motivate / appreciate our employees in terms of team building activities, positive attitude towards work culture, encouraging employee engagement and welfare.

## Format of ICS Ganesh Festival Celebration 2020:

During this festival the day starts with Ganesh Aarti for half an hour followed with Prasad for the attendees, then we all participated in Team Building games organized on virtual platform which counts as Inter Departmental Competition for about 1and half hour and then all moves on with our regular office activities/duties for the day.



On the Last day that means 11th Day, we all ICS family came together at one virtual platform, enjoyed online games and ended up with lot of good memories full of happiness along with positive energy to take this ICS Culture growing in next year's celebration.

### Rewards / Winning list as per activities:

Best Department (Winning Team for the Year 2020).  
Winner for Colour Code Male (followed for 11 days).  
Winner for Colour Code Female (followed for 11 days).  
Best Traditional Dress Male (for Last day of celebration).  
Best Traditional Dress Female (for Last day of celebration).  
Best Rangoli.

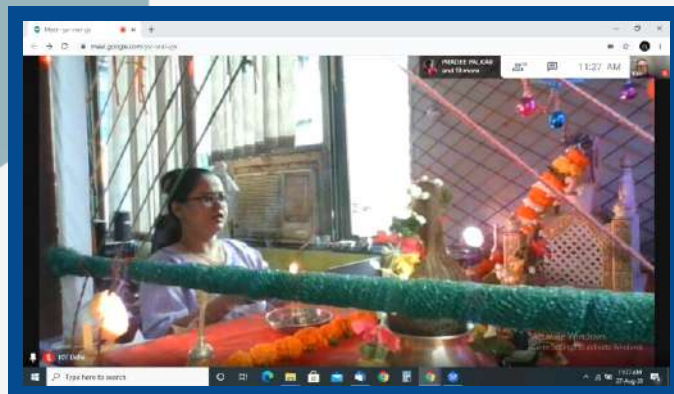
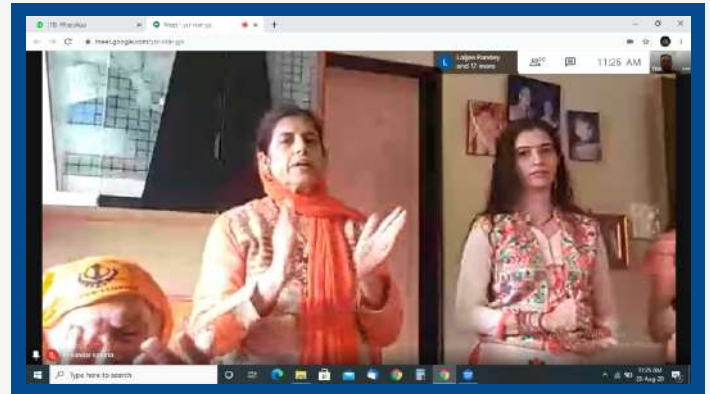
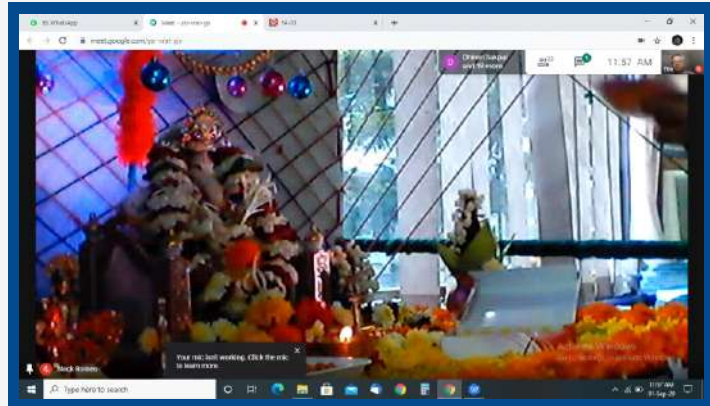
Finally, We take this opportunity to thanks our ICS Ganesh Festival Committee members and our management for their extensive support and beliefs for making this event successful and fruitful in pandemic.

Also heartiest thanks to every individual who have actively participated in this course of event without any hesitation for putting their efforts in terms of employee welfare, development and growth of our organization.

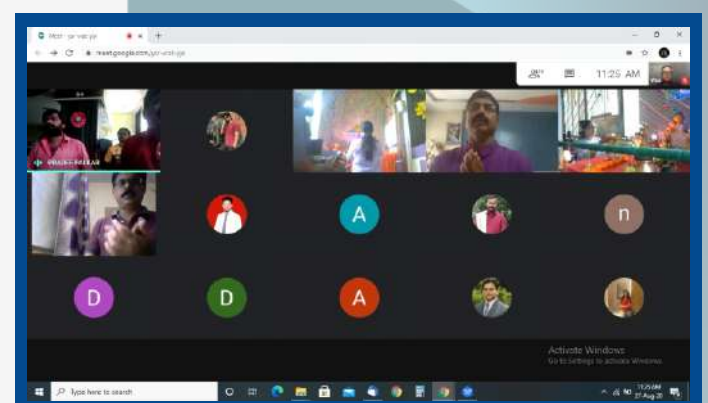
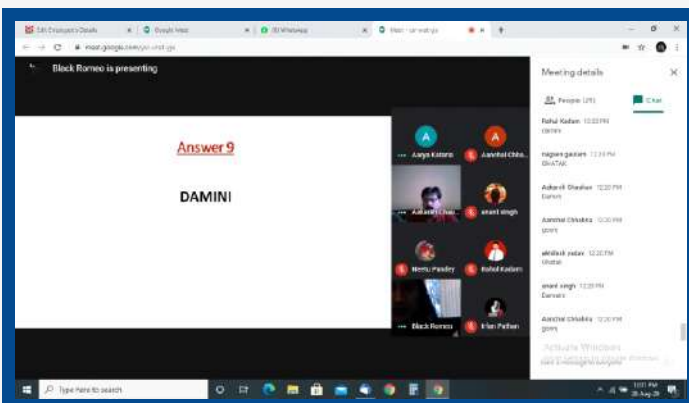
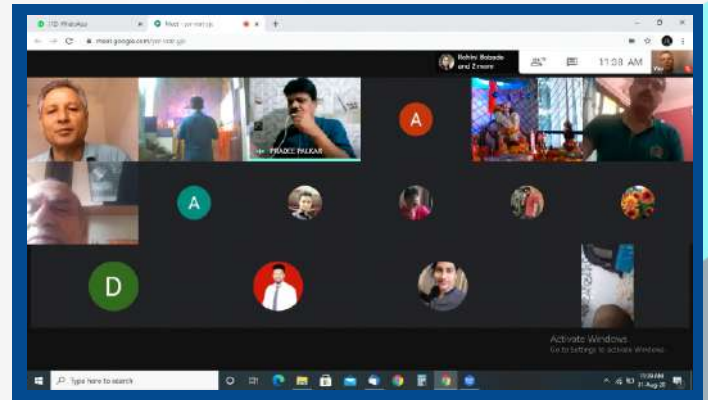
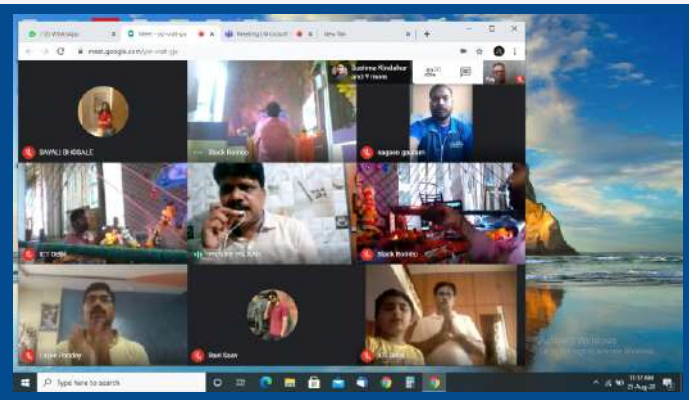
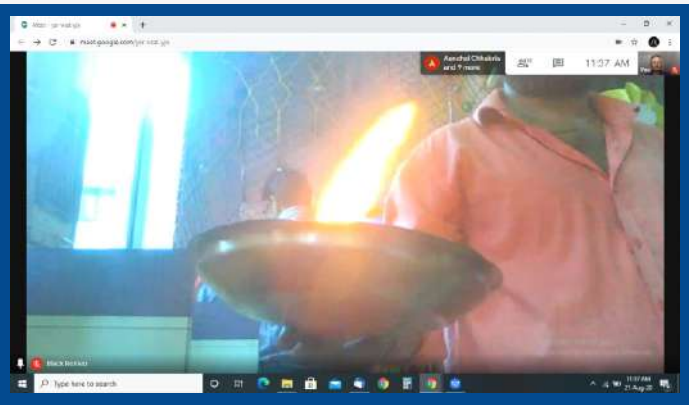
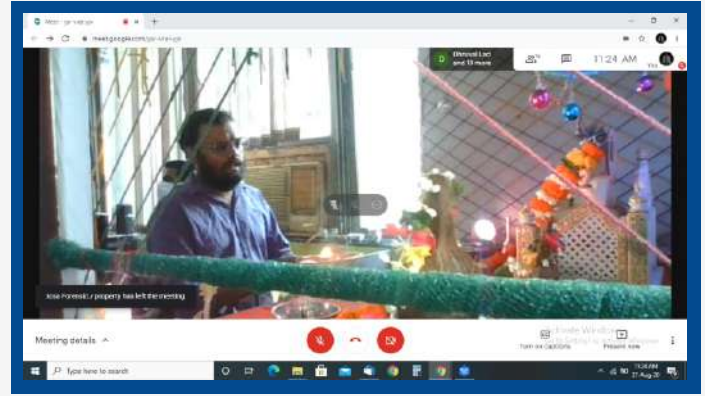
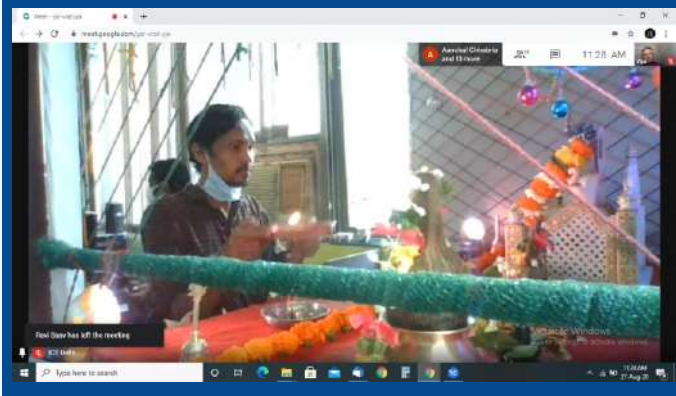
### Glimpse (Memories) of our Celebration 2020:












## New Achievement



File No. MD/NB/2018/37  
**GOVERNMENT OF INDIA**  
**Central Drugs Standard Control Organisation**  
**Ministry of Health & Family Welfare**  
**FDA BHAWAN, NEW DELHI (INDIA)**

Form MD-2  
 [See sub-rule (6) of rule 13]

**REGISTRATION CERTIFICATE TO BE ISSUED FOR NOTIFIED BODY**

**Registration Certificate No. RC/NB-000009**


1. M/s, International Certification Services Pvt. Ltd. situated at 22/23, Goodwill Premises, Swastik Estate, 178 CST Road, Kalina, Santacruz East, Mumbai-400098 (India), P :02242200900, 02226507777, F :02242200900, 02226507777 has been registered as a Notified Body of following Class A and/or Class B medical devices.

2. Details of Medical device(s):

S.NO	Standards for which it is registered	Class of medical devices
1	ISO 13485	Class A, Class B

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place : Central Licensing Authority  
 Date : 22-May-2020 [To be digitally signed]



मान्यता से / Recognition Number  
**FSSAI/TPA/2018-19/021(PR)**

**मान्यता प्रमाण-पत्र**  
**Certificate of Recognition**  
 (द्विदिनांक 5 वर्षों के लिए)  
 (5 year regulation 5)

प्रमाणित किया जाता है कि:  
 This is to certify that

**International Certification Services Pvt. Ltd.**  
**Mumbai.**

को भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा खाद्य सुरक्षा और मानक अधिनियम, 2006 के अधीन अनुवृत्ति प्राप्त खाद्य कारोबारियों की संपरीक्षण के लिए स्वीकृति दी गई है और यह खाद्य सुरक्षा और मानक (खाद्य सुरक्षा संपरीक्षण) विनियम, 2018 अधीन है, जिनका विशेषज्ञता क्षेत्र निम्न है:  
 has been recognised by the Food Safety and Standards Authority of India for the purpose of auditing of food business operators licensed under Food Safety and Standards Act, 2006 and subject to the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 with the following scope:

1. Food processing [i. Dairy ii. Slaughter houses iii. Meat and poultry processing units iv. Egg & egg products v. Fish & fish products vi. Other sectors]  
 2. Food storage / warehouse / cold storage  
 3. Food Transport 4. Food retail & Distribution /supplier  
 5. Food Catering 6. E-Commerce

यह प्रमाणपत्र दिनांक This certificate is issued / renewed on **28.08.2018** को जारी/नवीनीकृत किया गया है, जो दिनांक and is valid upto **27.08.2021** तक विद्यमान होगा

Dr. P. K. MITTAL  
 Director General of Food Safety and Standards  
 Government of India

## TRAINING CALENDAR

### TRAINING CALENDAR OCT - DEC 2020

Trainings	From	To	Fees	Time	Class Type
2 Days ISO 13485 : 2016 Internal Auditor	16-Oct-20	17-Oct-20	5000	10 to 2 pm	Virtual
1 Day Awareness Training on ISO 45001:2018 ( OHSMS )	29-Oct-20	29-Oct-20	3000	10 to 2 pm	Virtual
5 Days ISO 9001:2015 (QMS) Lead Auditor	19-Oct-20	23-Oct-20	14000	10 to 2 pm	Virtual
2 Days ISO 9001:2015 (QMS) Internal Auditor	13-Nov-20	14-Nov-20	5000	10 to 2 pm	Virtual
5 Days ISO 9001:2015 (QMS) Lead Auditor	24-Nov-20	28-Nov-20	14000	10 to 2 pm	Virtual
2 Days ISO 22000:2018 (FSMS) Internal Auditor	17-Dec-20	18-Dec-20	6000	10 to 2 pm	Virtual





## INTERNATIONAL CERTIFICATION SERVICES

Please send your valuable comments and suggestion on "suggestions@icsasian.com". To subscribe for freesubscription send us a mail with subject "subscribe for "Quality Mantra"" at suggestions@icsasian.com

### CORPORATE OFFICE

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Tel: 022-26507777-82, 42200900, Email: info@icspl.org / Web: www.icspl.org

### BRANCH OFFICE

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\*Kanpur \*Kolhapur\* Kolkata \* Ludhiana\* Mumbai\* Dombivali\* Nagpur\* Nasik\* New Delhi\* Pune\*  
\*Rajkot\* Surat\* Udaipur\* Vapi\*

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