

Medical Devices





Dr. Sundar Kataria
Chairman & Managing Director
International Certifications Services

Dear Friends & Business Associates,

We hope you all, your families and friends will be well, safe, sound and secure.

Today we all are very much concern about the Medical Devices which are being used by us and by the Medical Practitioners. Are these Medical Devices safe and effective?

Under the Prime Minister Modi's vision to be "Atmanirbhar Bharat" by promoting indigenous supply "Made In India", Government of India gave thrust and encouraged new enterprises to manufacture the Medical Devices in India towards self-reliance. Until early 2020, we have been importing essential items like simple PPE to ventilators from abroad. However Covid-19 has given excellent opportunity to develop and manufacture above as well many medical devices in India under "Make in India"

Few years ago Medical Devices produced in India were from unorganized sector of Industry therefore Quality and Performance was big question mark? Very recently in the year 2017, it has been regulated by having "Medical Devices Rules" that was revised this year, 2020. The Regulatory Authority, CDSCO is responsible for control of the Quality and Safety of Medical Devices in India.

The Quality Council of India adopted the Medical Devices Management System based on International Standard ISO 13485, Quality Management System for Medical Devices. This management system will ensure quality and effectiveness of the medical devices.

Our country is fourth medical device producer in the world with revenue generation of approx. \$10 billion and expected to be \$50 billion by the end of 2025.

Problems associated with the medical devices are too many because of unawareness, its manufacturing, failures and life cycle including malpractices. The risk related to Covid-19 provided very big opportunity as more than 500 new entrepreneurs and manufacturer entered in this business whereas we had only 1000 manufacturers and services provider in the past. Today we not only manufacturer but also export to number of countries. The Medical Devices produced in India recently covered overall and caps, ventilators ,rapid diagnostic kits and Covid-19 diagnostic kit thus contributing in earning of foreign exchange for the country including saving of foreign exchange. India has many fold advantages and benefits to produce Medical Devices in India.

- High level of expertise
- Low labour cost
- Government incentives – SMSE
- Government funding for R & D
- 100% FDI
- Medical Tourism
- Shift from China

Thanking you,

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



Dilip Negi
General Manager
Manager (Admin/HR)

Sat-Gun-Sang - An Initiative of Knowledge Sharing

Sat, Gun & Sang are three Sanskrit words. Wherein the first word is derived from famous mantra of Brhadaranyka Upnishad (1.2.28) असतो मा सद्गमय। तमसो मा ज्योतिर्गमय। मृत्योर्मा मृतं गमय॥ means Lead us from delusion to truth, from darkness to light, from mortality to immortality.

Sat (Sanskrit सत्) is a Sanskrit word meaning "true essence", which is unchangeable. In simple word it means true and genuine.

Gun (Sanskrit गुण) meaning "Quality, characteristics, merit, virtue. Because of this single word our Quality Fraternity exists on this planet. Our ancient literature is full of description about three states of quality - Sattva (associated with creation), Rajas (associated with preservation) and Tamas (associated with destruction).

Sang (Sanskrit संग) means association, union connection.

Thus Sat-Gun-Sang means an association of like minded people who are seeking true essence of quality in their life and sharing this knowledge with community.

Sat-Gun-Sang is brain child of Dr. Sundar Kataria, where he was looking for a common platform for sharing acquired knowledge by various quality stalwarts, quality controllers, quality managers, clients and even by common man. Human species is a creature which borrows from society everything (including knowledge) since birth to his death. Also fulfillment in life comes in 2 ways - 1. When knowledge is gained and 2. When knowledge is shared. Hence it is our moral duty to give it back to the society from where we borrowed it. If you do not return to society same will be buried with you at the time of death.

ICS is main propeller behind this initiative under the leadership of Dr Kataria in association with SJK Foundation - a charitable trust and its knowledge partner ICS Technologies. Till date we have organized various knowledge sharing drives in the form of awareness programme, experience sharing and problem solving workshops of various quality related subjects.

In current pandemic situation it has become more relevant to discuss practical issues related to our day-to-day operation in various sectors. Current time is very challenging and the best way to survive is to do more and more brain storming.

As Dr. Ravi P. Singh, Secretary General of Quality Council of India rightly said: "Organizations who have invested in Quality, have sustained during the pandemic." We request you all please join us in this noble initiative because we believe the lamp of knowledge shall always illuminate the life of next generation of emerging entrepreneurs, engineers, QA/QC personnel, clients, customers and even a common man.



Sudesh Sharma

Radiation processing of food and medical products.

Radiation Processing

Ionization radiation has high energy which is enough to break the molecule bond and ionize atoms. As a result, materials exposed to radiation undergo modification in their physical, chemical and biological properties. At present the principal industrial applications of the radiation are sterilization of health care products including pharmaceuticals, medical devices, food and agriculture products (for various end objectives such as disinfection, shelf life extension, sprout inhibition, pest control and sterilization etc)

Gamma processing has several advantages over other treatment methods for example sterilization of health care products using EtO into wet steam as a sterilant whereas Gamma Sterilization has many advantages include

- Products of any Shape as powerful gamma rays can penetrate into through packaging and products.
- Cold process does not effect sensitive plastic medical devices and pharmaceutical products. The value of iridium is prescribed by the Radiation Expert.
- Flexibility in packaging.
- Sterilization is effective after packaging prevent contamination and undamaged products.
- Efficient as continuous and automatic process with simple single radiation cycle parameter to be controlled.
- The treated products can be used immediately.
- The radiation process is precise and reproducible treatment.

RADIATION STERILIZATION AND HYGIENIZATION

In radiation process a product and material is irradiated to preserve, modify or improve its characteristics. It is simple and safe process involving exposure of the products or materials to ionizing radiation emanating from the iso type service such as Cobalt-60 for a pre determined time. So as to impart a prescribed dose according to the product. A fraction of the radiation energy that reacts the product is absorbed by the product, the amount of radiation depends on its mass and composition, its time of exposure



However the product is irradiated by Gamma rays does not become radioactive . Thus safe and can be handled normally.

The medical devices are primary packed in poly packaging material with a secondary packed in the card board boxes / cartoon or aluminum tote boxes.

The minimum irradiation radiation given is 25 kilo gray to control micro bid count of (-10^3 CFU per unit), the probability of any microbial survival can be expected to be less than one in one million.

Products commonly sterilized by radiation.

Medical devices and pharmaceutical products are compiled with Medical Services Rules 2017 and Cosmetic Act Rules, 1945 respectively and cleared by Food and Drug Administration and CDSCO

Absorbent Cotton Wool and Absorbent Gauze Products

1. Bandages - Crape, cotton crape, gauze
2. Cotton - buds, pads, swabs
3. Dressings - finger dressings, first field dressings, paraffin gauze dressings, shell dressings Kits - Maternity/Dai, Minor Surgery, Vasectomy
4. Sutures: with or without needles (Absorbable/Non-absorbable) - catgut, linen, polyester and silk
5. Hemostate Medical Devices: Absorbable gelatin sponge, Perfusion sets, Hypodermic syringes and needles, Intra-uterine contraceptive devices (IUCD)
6. Pharmaceuticals, Powders and Others: Debrisan, Neomycin sulphate powder, Prickly heat powder (containing boric and salicylic acid), Fluorescein sodium strips, Catalin tablets

Ophthalmic Ointments in Paraffin Base

1. In Collapsible Aluminum Tubes: Atropine Sulphate, Chloramphenicol, chlorotetracycline, Gentamycin sulphate, Neosporin (Neomycin sulphate, polymixin, and bacitracin), Tetracycline
2. In Soft Gelatin Capsule: Chloramphenicol
3. Skin Ointments in Polyethylene Glycol Base: Neomycin sulphate Hydro- cortisone acetate, alpha chymotrypsin
4. Cosmetics : Artificial eyelash, Eyebrow pencil, Face powder, Kajal, Lipstick, Talcum powder
5. Veterinary Products : Quinapyramine chloride and sulphate

Ayurvedic Products and Raw Materials

1. Special Products (mainly for export) : Belladonna dry extract, Ergot Powder, Papain, Rawolfia serpentine

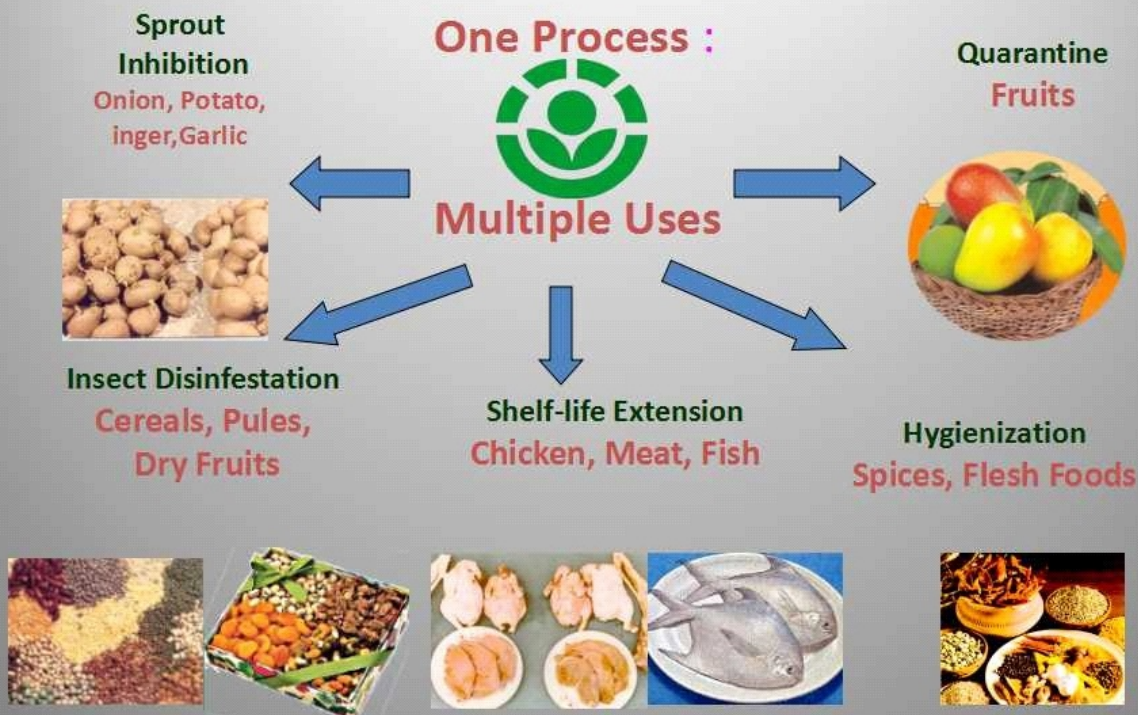
List of the Products not covered under Drugs and Cosmetic Act Rules, 1945

1. Cellulosic : Nappies, Sanitary napkins, Tampons, Umbilical cord tapes
2. Metallic Products: Aluminum caps and containers, Empty aluminum tubes (collapsible), Orthopaedic implants, Surgical blades, Surgical tools
3. Plastic and Rubber : Cannulas, Catheters (Folley, Gibbon etc.), Pharmaceutical Containers/Closures, Droppers (eye, nasal), Plugs and sprinklers, Drapes (polyethylene), Forceps, Hydrocephalus shunts, Latex rubber gloves and Bungs, Petri dishes, Scalp vein sets, Shunt valves, Silastic rings, Tapes (for sealing), Trays, Trolley Covers, Tubings (endotracheal, duodenal, feeding, Ryles etc.), Urine drainage bags

The certification of the ISO 13485 : 2016 ensures the legal and regulatory compliance in accordance with the MDR, Medical Device Rules , 2017 amended 2020.



Radiation Processing of Foods





Dr. Sundar Kataria
Chairman & Managing Director

CLASSIFICATION, PROBLEMS, ADVANTAGES OF MEDICAL DEVICES

CLASSIFICATIONS OF MEDICAL DEVICES

- **CLASS I** - Least Risky and Invasive category. Minimum contact with the patient & low impact on the patients overall health. It do not come in contact with patients internal organs, the central nervous system or cardiovascular systems
- **CLASS II** - These are more complicated than CLASS I, present higher risk. These comes into sustained contact with patients internal organs, cardiovascular system including IVD Diagnostic tools / instruments.
- **CLASS III** - The devices are usually sustain or support life and implanted or present in the potential unreasonable risk of illness or injury like permanent implant, smart medical devices and life support system

EXAMPLES OF CLASSIFICATION OF MEDICAL DEVICES

CLASS I

Electric Tooth Brush
Tongue Depressor
Oxygen Mask
Reusable surgical scalpal
Bandages
Hospital beds & furniture

CLASS II

Catherers
Blood pressure cuffs
Pregnancy test kits
Blood transfusion kits
Contact lenses
Surgical gloves
Absorbent sutures

CLASS III

Breast Implants
Pace makers
Defibrillators
High frequency ventilators
Cochlear implants
Foetal blood sampling monitors
Implanted prosthetic

MEDICAL DEVICES

- 1.HOSPITAL FURNITURES
- 2.DISPOSABLES
- 3.MEDICAL DEVICES AND EQUIPMENTS
- 4.IMPLANT
- 5.PPE
- 6.TESTING KITS
- 7.INVITRO DIAGNOSTIC PRODUCTS
- 8.CONTRACEPTIVES
- 9.REAGENTS
- 10.DRUG CHEMICALS - EXTERNAL USE
- 11.SIMPLE TONGUE DEPRESSORS
- 12.BED PANS
13. PROGRAMMEABLE PACE MAKERS - IVD SYSTEM
- 14.CLOSE LOOP ARTIFICIAL PANCREAS
15. VENTILATORS
- 16.IN VITRO DIAGNOSTIC PRODUCTS
- 17.REAGENTS
- 18.RAPID TEST KITS / TEST KITS
- 19.BLOOD GLUCOSE METERS
- 20.CONDOMS
- 21.LUBRICATING GEL
- 22.OPHTHOLOGIC EYE DROPS & GEL
- 23.CALIPERS
- 24.WHEEL CHAIRS
- 25.WALKERS



PROBLEMS GENERALLY REPORTED WITH MEDICAL DEVICES

- User considerations - Ability familiar with devices, training and qualifications
- Resources - Skilled doctors / Technician, Nurses and support staff
- Unaware of legal and regulations
- Poor commitment
- AMC - Annual Maintenance control
- Single use / recycled
- Poor quality control and quality assurance
- Self life and life cycle
- Poor Packaging
- Defects
- Inadequate Instructions / Labeling / Packaging issues.
- Interaction with th devices - Configuration management
- Malfunction / work as intended
- Sterilization performances
- Environment
- Software problems
- Errors - Inconsistent results
- Reusable and / or Reprocessing
- Human factor - Untrained and user characteristics
- No calibration and poor maintainence

ADVANTAGES

- High level of expertise
- Low labour cost
- Government funding for R & D and Laboratories
- Medical Tourism - Most favored destination
- Huge domestic requirements
- Shifting manufacturing from China (OEM)
- Incentives to SMSE



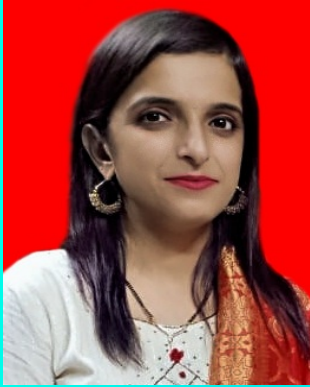
Sonika Rani

Steps to check Authenticity of ISO certificate

1. Check whether the certificate has both the logo of certification body & accreditation body.
2. In case there is no accreditation body logo, its non-accredited certificate and legally not valid to be part of international system.
3. If the accreditation body logo is there, check if the accreditation body is the part of IAF (International Accreditation Forum) from IAF website link i.e. https://www.iaf.nu/articles/IAF_MEMBERS_SIGNATORIES/4 with respect to country.
4. If the accreditation body name is listed, check whether it provides accreditation for the respective standard.
5. After confirming the accreditation body name, logo & accreditation standard, check the certification body name, scope & certificate validity listed in the accreditation body website database.

For Example:

- NABCB is the accreditation body in India. Check the certification body name listed in NABCB website link i.e. http://nabcb.qci.org.in/accreditation/reg_bod_mdqms.php for MDQMS.
 - Click on the certification body name and check whether it is authorized for the scope in which your activity falls & then check the certificate issue date on your MDQMS certificate whether it is within the date range of 'valid from' & 'valid upto'.
6. If your certificate meet these above conditions, the certificate is VALID.
 7. If in case, you have any doubt or could not find the link to verify the certificate, refer the copy of the certificate to the concerned accreditation body for verification.



Jarna S Mandhyan
Senior Office Executive

POINTS TO BE TAKEN IN MIND WHILE BUYING MEDICAL THINGS.

OXYMETER

Lets see what things we will consider before buying it.

1. What is an oximeter?

Pulse oximeter (also called pulse ox) is a non-invasive device that calculates the amount of oxygen in the blood. It is a small device that looks like a clip. You have to press the clip, place your finger (nail side up) inside and within seconds it gives you your readings. Most healthy people get an oxygen reading of around 95 to 99 per cent.



2. Is there a specific finger which we should use?

Most commonly the index finger is used to take the reading. So in case you are right-handed, use the middle finger of your right hand and if you are left-handed, use the left middle finger.

3. Accuracy of a pulse oximeter

Pulse oximeter gives 98 per cent accurate results and has an error window of only 2 per cent. This means that the oxygen levels in the blood can be 2 per cent above or below the readings shown by the oximeter.

4. Is oximeter easy to use?

A pulse oximeter is a fairly easy to use device and that is why doctors rely on it, despite a 2 per cent error window.

5. Can external factors affect oximeter reading?

Yes, some external factors can affect the oximeter reading. Putting dark nail paint on nails or extremely cold weather can give a false reading. It is recommended to remove any dark nail paint before using an oximeter.

Also there are few other questions

1. How accurate is the oximeter and is the accuracy claim backed by evidence, e.g., studies and published papers?

2. Will the oximeter work on a variety of patients? Does your oximeter specifically claim accuracy for patients with low circulation or dark skin tones?

3. Will one device work for different patient size ranges, including very small fingers up to large fingers, or will I need to buy two separate oximeters?

4. Who offers the best warranty and has the best reputation for excellent customer service?
5. Where is the oximeter manufactured, and who will I call if I have a problem with my oximeter?
6. How long can I expect to use the oximeter? (If a device does not last, a lower upfront cost can result in higher costs due to multiple replacements.)
7. Is the oximeter easy to use and does it have a large, easy-to-read display?
8. Does your oximeter let you know if your finger is not placed correctly in the device?
9. Does the oximeter introduce lead or other hazardous materials into the environment? Does it comply with international lead free and/or hazardous materials standards?

Now when we are buying WEIGHT MACHINE lets see what points will we consider before buying.

Weighing Machine Brand Name:

The first and the most important thing that you should consider while purchasing a new weighing machine is the brand name. As said, there are numerous brands for weight machine in India, you may find it difficult to choose the perfect one for yourself, and on the other hand, you may also fall for the new or lesser-known brand that sells the cheaper scales. However, if you are really looking forward to buying a good product for yourself then choosing a renowned brand with lots of user reviews will help you opt for a product that has a better warranty, list of features, workmanship, and reliability. So, instead of falling for cheaper brands, try finding a good brand that is trending the store. By choosing a good brand, you can be assured of the quality and efficiency of the scale that makes it a worthy decision for you.



Weighing Machine Usability

Another important thing that you must consider while purchasing the weight machine is usability. Most users buy a smart weight machine with numerous such function that they don't know about. BY doing so, the overall value of the product decreases, as you won't be able to use it properly. So, instead of falling for the high-end weight machine with lots of features that you haven't heard of before, try buying the basic one according to your needs. Make sure to choose a machine that is easy to use and doesn't have complex functions that you aren't aware of. By doing so, you won't only be able to buy a suitable weight machine for yourself, but will also avoid buying a product that is not the right choice for you.

Weighing Machine Type

One of the most important things to be considered while purchasing a new weighing machine is the right type of the weighing machine. The weighing machines have a very clearly classified field and it is essential that you choose the best one for yourself to get the most effective and accurate results. So, make sure that you are well aware of your needs and types of a weight machine in the market and then choose the most perfect one for yourself. BY choosing the right type for yourself, you can be assured of getting the best results and best value for your money.

Weighing Machine Value for money

Have a look at the features of the machine and the brand value, and then judge whether the pricing of the product is right or not. By doing so, you can buy a product that perfectly justifies its value. So, make sure that you are examining the product completely before making the purchase.

Weighing Machine List of features

The last thing that you should look for while purchasing a new weighing scale for yourself is the list features. The feature list not only justifies the price of the scale but also provides you with great usability. Make sure that the weight machine you are planning to buy has all the required features that you are looking for. Also, make sure that the features are fairly easy to use. By doing so, you can be sure of getting a perfect product for yourself.

Testimonials



Date: December 10, 2020

To,
International Certification Services Pvt. Ltd.
Mumbai

Sub: Thank-You Note

Sir,
We would like to thank International Certification Services Pvt. Ltd. for our ISO 13485:2016 certification.

ICS is best in class and the team is approachable at any time for any help. Also they help us with suggestions to improve our processes & compliance.

Yours Sincerely,
For 3B BlackBio Biotech India Limited




Shirish Anand Koshu
General Manager



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KONIKKARA INDUSTRIES
Creativity is our passion. Quality... Obsession.

Date: December 14, 2020


To,
International Certification Services Pvt. Ltd.
Mumbai

Sub: Thank-You Note

Sir,
We would like to thank International Certification Services Pvt. Ltd for our ISO 13485:2016 Certification.

ICS is a very professional organization with Highly Experienced Auditors and are very much helpful in guiding towards the best possible improvements in processes and compliances.

Yours Sincerely,
For Konikkara Industries, Bangalore

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Karnataka,India.

TRAINING CALENDAR DEC 2020

TRAINING CALENDAR DEC 2020					
Training	From	To	Fees	Time	Class Type
2 Days ISO 9001:2015 (QMS) Internal Auditor	7-Dec-20	8-Dec-20	6000	10 to 3 pm	Virtual
5 Days ISO 9001:2015 (QMS) Lead Auditor	20-Dec-20	24-Dec-20	16000	10 to 3 pm	Virtual
2 Days ISO 22000:2018 (FSMS) Internal Auditor	28-Dec-20	29-Dec-20	6000	10 to 3 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

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