ELLECOM®

Connected.Committed to Community

OUR VISION, MISSION & VALUES

Following its motto to connected and committed to community, Ellecom's vision, mission and values converge to improve the quality of life

Providing assuredly effective and efficient solutions and products for furthering our dream of a united community where everyone is healthy and has an opportunity to succeed is our vision.

To improve the quality of life, our mission is to explore opportunities and resources to improve quality of life with our products and solutions. Keeping in mind the safety of success, we can achieve the goal of our mission through working together with people. They are the center of our thinking and doing.

We believe that our values are important as they help us grow and develop. As an organisation, we make hundreds of decisions everyday. Our values help us to create the future we want to experience. Ellecom values can be encapsulated in the following:

Clarity : in thought and actions keeping in mind the Goals
Trust : Openness, Transparency and Entrepreneurship
Loyalty : Interest of the company and community at large
Pride : Part of the team which works for the communities' benefit
Respect : Diversity of opinions & Inclusivity

The Idea

Ready

Ellecom GmbH becomes operational in 2020

As a subsidiary of Ellecom Swiss AG, Switzerland.
But it has been a work in progress of our Managing Director, Rohit Zutshi for several years.

Steady

Ellecom GmbH gradually adapted

After starting initial operations in Electronics especially in obsolete and rare-to-find components, we adapted within a very short span to successfully venture in the Medical products and In-Vitro diagnostic products.

and Go.....

Ellecom designs and executes customised projects

We work with the manufacturers specialised in the production of medical goods and services across Asia and Europe. We offer our expertise to help facilitate these manufacturers meet project specific requirements.

Reinventing

Changing regulatory framework in EU

In the background of implementation of EU MDR (2017/745) and EU IVDR (2017/746), we believe that reinventing business models and building sustainable sources have never been more important for healthcare industry, especially when seeks to improve lives and livelihoods.

Strategy

With large international manufacturer base and reliable logistics partners

We, committed to business-building built a corporate strategy and allocated resources to acquire requisite competency. Over the years, we have developed sustainable business relations with the various stakeholders at national and European level. The knowledge and network- based methodology gives, Ellecom the edge to be competitive in the market.

Ellecom GmbH is a limited liablity company which came into existence in the year 2020 and conducting its business operations from financial capital of the Eurozone, Frankfurt. It is a subsidiary of Switzerland based public limited company Ellecom Swiss AG (formerly known as Infotainment Systems AG)

The journey started in the year 2017 with Ellecom Swiss AG (previously known as Infotainment Systems AG) which led to formation of another legal entity in the form of Sole Proprietorship, Ellecom in 2019. The journey from sole proprietorship to limited liability company completed in 2020 when Ellecom GmbH came into existence. The year 2021 marked the creation of another subsidiary Ellecom SGI Pvt. Ltd. based in India.

Ellecom GmbH initially started its business operations in Electronics especially in obsolete and rare-to-find components making international purchases for its customers/clients, in the healthcare and electronic sector, procuring products and components when they are hard to find, especially when the supply is limited due to the excessive demand. During the process, Ellecom GmbH worked very closely with its logistics partners having impeccable track record in international trade but most importantly Ellecom GmbH invested its resources, in terms of finances and workforce, to work with manufacturers based out of different parts of world specialized in large scale production of Medical Products and In-Vitro Diagnostic products. With the acquired knowledge and expertise, Ellecom GmbH started designing and executing customized projects as per client's requirement.

Ellecom GmbH used data, talent, distribution, and brand for providing differential capabilities while still prioritizing quality and access. Ellecom GmbH developed institutional connections involving Competent Authorities, Notified Bodies, Financial Institutions, Think Tanks, Organisations for Interest Representation at various institution of the European Union.

Medical Device and In-Vitro Diagnostic Sector

Innovation is an important aspect of multifaceted Medical Device and In-Vitro Device Industry which makes it challenging and exciting. The other important aspect which adds an additional layer of challenge and excitement is regulatory compliance. Major shifts in regulatory requirement makes it increasingly difficult for the companies working in this field to sustain.

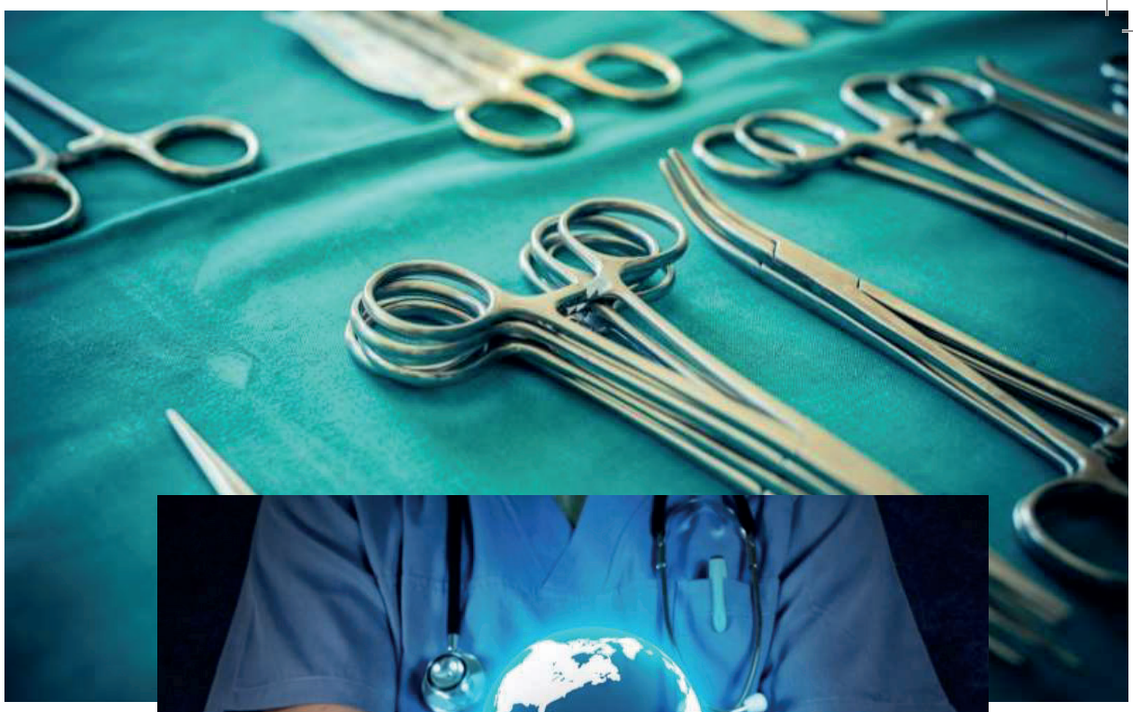
MAJOR SHIFT

Regulatory framework is a tool to boost patient safety but more importantly to increase transparency to make the process clearer for everyone involved. From Manufacturer perspective, the balance between continual innovation and regulatory requirement is a key to sustain and grow. Introduction of new Medical Device Regulation (MDR) and In-Vitro Diagnostics Regulation (IVDR), the landscape in the European market has undergone a tremendous change affecting all the players involved but especially global manufacturers involved in manufacturing medical devices and in-vitro diagnostic products.

The balance is disturbed giving rise to uncertainties and unknowns. Insufficient number of designated notified bodies, delay in the EUDAMED implementation and lack of sufficient guidance documents is leading to a lot of guess work. In addition, much greater emphasis has been placed on clinical data, clinical evaluations, and post-market surveillance and all this must be reflected in the manufacturer's technical documentation and quality management system. The regulations have resulted in up -classification of several devices which require involvement of notified bodies, and it has a huge impact for IVD manufacturers as over 80% of IVDs need notified body involvement. In addition to above-noted European regulations, there is an additional layer of country specific rules, processes, and registration requirements which goes beyond European market.

These challenges will not disappear soon as the situation may lead to reduction in willingness of the players to innovate and bring new products to the market, but we can hope that the long future holds safer and better performing devices in the market and a harmonized approach.

REINVENTION: NEED OF THE HOUR



The evolution toward new business models is key for sustenance in healthcare industry, which is driven by rapid development of medical science, extreme fluctuations in market demand, complex labyrinth of government policies and unpredictable financial pressures. In the background of ongoing COVID-19 pandemic and changing regulatory framework which has already started with implementation of EU Medical Devices Regulation (2017/745) and EU In-Vitro Medical Devices Regulation (2017/746), Ellecom believes that reinventing business models and building sustainable means have never been more important for healthcare industry, especially when it seeks to improve lives and livelihoods.

Market for new business innovation has accelerated during the pandemic. What was previously done in years must now be done in months and that which was done in months in a matter of weeks. Sensing the significant scope for improvement in healthcare and potential for returns, Ellecom has deployed substantial capital and talent from within and beyond healthcare with a goal of driving new business creation and scale-up through reinventing its business with the speed of the market.

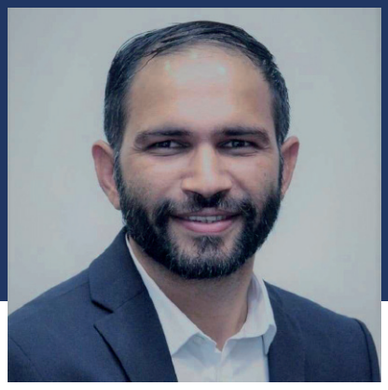
In view of the new European regulatory framework (MDR (EU) 2017/745) and (IVDR (EU) 2017/2017), European Authorised Representative acts as a regulatory interface between Manufacturer and the Authorities (National and European). Ellecom GmbH is positioned to establish strong regulatory support to keep its clients on the forefront of European Regulatory requirements. By following strong compliance protocol as per MDR and IVDR, we keep our clients up-to-date on the changes in the regulatory framework. In the process of ensuring full compliance with products registrations, we ensure privacy of confidential business information and store safely the copy of technical documentation and other files requested under MDR and IVDR to make them available to national authorities. We liaise with EU authorities on corrective action and keep track on Post Market Surveillance to communicate to the parties involved on any findings.

Recognition Agreement between EU and Switzerland ceased to apply for medical devices. Switzerland enacted a revised version of its Medical Device Ordinance, SR 812.213 (MedDO), which has introduced additional requirements to account for the absence of an updated MRA. As per the revised MedDO, medical device manufacturers established in EEA countries, or established elsewhere and represented by EU Authorised Representative located in a EEA country, now need a Swiss Authorised Representative to sell their CE-marked devices in Switzerland, just like medical device manufacturers from outside the Union market. Ellecom Swiss AG with its German subsidiary Ellecom GmbH is uniquely positioned to offer Swiss Authorised Representative services ensuring compliance with registration requirements in Switzerland.

Ellecom GmbH will consistently provide products and services that meet or exceed the requirements of its customers. It will always ensure zero defects, timely delivery and compliance to all legal and regulatory laws. It will actively engage in activities for continuous improvement of quality and service.

The Inspiration

With more than 20 years of professional experience, our Managing Director, Mr. Rohit Zutshi is an alumns of prestigious University of Bonn, Germany where he completed his Masters in European Studies. Rohit believes in identifying the human aspect in every business idea.



CERTIFICATE

DEKRA

ELLECOM®
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ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the organization

Ellecom GmbH

Scope of certification:
Sales & Distribution of Electronic Components,
Medical devices and In-vitro Diagnostic devices

Certified location:
Friedrich-Ebert-Anlage 49 (Messeturm), 60308 Frankfurt am Main, Deutschland

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A20121218.

Certificate registration no.: 91021774
Validity of previous certificate:
Certificate valid from: 2021-10-20
Certificate valid to: 2024-10-19

Language translation

Dr. Gerhard Nagel
DEKRA Certification GmbH, Stuttgart, 2021-10-20

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra.de/audits

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NOTE

FROM MANAGING DIRECTOR

Since my university I have been interested in the anthropological and sociological aspect of work dynamics, knowing that the future is becoming more global, more complex and more networked every day. For this reason I founded Ellecom, a homogeniser of very different business and corporate cultures, but which is increasingly being asked to work together.

Inspired by the well known idea by Mr. Zig Ziglar, "You don't built a business, you build people, and then people build the business", I believe that we should be more focused on the human aspect. After all, our collective imagined reality of corporate and legal entities are based on well being and growth of human beings.

Rohit Zutshi
Managing Director