



TÜV Rheinland Italy issues the CE certificate according to MDR to ASENSUS 02.02.2023 | Pogliano Milanese (MI)



TÜV Rheinland Italia,
Notified Body in
Testing, Inspection, and
Certification services,
delivered to **ASENSUS**
the CE1936 certificate
in accordance with the
new EU Regulation

2017/745 for the SENHANCE® laparoscopic surgical robot,
a new frontier in the field of minimally invasive surgery.

The certification process was characterized by multidisciplinary, in which several technical experts, clinicians, and qualified resources collaborated, all involved in the analysis of the specifications, designed to ensure the best possible results. During the testing activities, the laboratories of the TÜV headquarters in Pogliano Milanese, among the most advanced, were also involved, especially for electromagnetic compatibility (EMC) and electrical safety (SAF) assessments.

The achievement of this milestone was made possible thanks to the high level of research in the field of robotics by ASENSUS, which has been able to create and finalize innovative products and develop technical skills that, with the intervention of TÜV Rheinland Italia and the high-profile technical professionals made available for the evaluations required by EU Regulation 2017/745 and UNI EN ISO

13485:2016, in respect of each other's roles, has led to the marketing of medical devices of important and high technological level, guaranteed by the CE1936 certification of TÜV Rheinland Italia.

The collaboration with an advanced reality such as ASENSUS enhances the mission of our activity in the medical field, which is to evaluate medical devices according to Regulation 2017/745, guaranteeing maximum commitment and scrupulousness in the use of resources, knowledge and methodologies necessary to ensure product safety.

The importance of obtaining certification in accordance with MDR means certifying one's products in accordance with one of the most advanced regulations in the sector, and thus making safe and performing devices available to the market, confirming attention to the evolutions required for medical device safety.

TÜV Rheinland Italia confirms its professional features of competence, dedication, and scrupulousness, fully aware of the importance of its work for the community, and for the industrial world, continuing to represent a certainty to rely on, as well as a point of reference in this complex, but necessary, transition to the new EU Regulation 2017/745.

TÜV Rheinland is a global leader in independent inspection services, founded nearly 150 years ago. The group maintains a worldwide presence of more than 20,000 people; annual turnover is EUR 2 billion. The independent experts stand for quality and safety for people, technology and the environment in nearly all aspects of life. TÜV Rheinland inspects technical equipment, products and services, oversees projects, and helps to shape processes

and information security for companies. Its experts train people in a wide range of careers and industries. To this end, TÜV Rheinland employs a global network of approved labs, testing and education centers. Since 2006, TÜV Rheinland has been a member of the United Nations Global Compact to promote sustainability and combat corruption.

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