



## Quality Policy

Specialized in high technology in the service of medical diagnosis, we base our QSE approach on the complete satisfaction of our customers and compliance with the international regulations relative to our business line.

In this regard, DMS Imaging implements a documented quality management system and maintains its efficiency to promote a progressive approach among all members of staff.

Therefore, we commit to:

- implement an organization allowing us to identify the expectations and needs of our customers.
- deploy the processes contributing to the satisfaction of our customers, our employees and our shareholders.
- identify possible deviations and address them in order to obtain better performance in terms of cost, quality and time.
- take into account, permanently, the people's safety.
- improve our image as a company responsible and respectful towards the environment.

Requirements from these standards and regulations are met:

- ISO 13485:2016
- ISO 9001:2015
- The applicable European medical device regulations:
  - o Directive 93/42 EEC and article 120 of Regulation (EU) 2017/745 relating to medical devices during the grace period.
  - o Regulation (EU) 2017/745 between 26/05/2021 and 04/05/2023 for all new products or significant changes to existing medical devices.
  - o Only Regulation (EU) 2017/745 from 04/05/2023.
- Code of Federal Regulations, Title 21 Part 820 (USA)
- Medical Device Act, Taiwan
- Medical Device Act, KGMP Regulations (Korea)

All the regulations applicable to our products are available in the document E\_PS02-030.

The Quality & Regulatory Affairs Manager is responsible for ensuring that these commitments are respected, as the Representative of the Management, and promote a continuous improvement spirit among all entities of the DMS Imaging division.

The persons responsible for regulatory compliance (PRRC) actively participate in ensuring compliance with the regulation according to article 15 of Regulation (EU) 2017/745.

These provisions aim for the perpetuation and the evolution of the DMS Imaging division.

**Samuel Sancerni**

DMS Group Managing Director