ASG QUALITY POLICY [SBU Medical Systems]

1 SCOPE

The present Quality Policy applies to all Medical Devices of ASG Superconductors S.p.A.

2 REFERENCES

Reports	Description / Standard point
MDR 2017/745	Regulation for all Medical Device Manufacturers in the EU
EN ISO 13485	QMS required by essential requirements of MDD/MDR: • 4.1.1: Quality management system (general) • 4.1.2: Quality management system (general) • 5.3: Quality Policy • 5.4.1: Quality objectives
QMSR (21 CFR 820)	FDA QMSR requirements
SOR 98/282	Canadian Medical Device Regulation
MDSAP	Medical Device Single Audit Program
ISO 9001	QMS requirements (general)
ISO 14971	Risk Management for Medical Device

3 QUALITY POLICY

ASG Superconductors S.p.A. is committed to provide innovative Magnetic Resonance Imaging units for the area of Diagnostic Imaging by achieving, and sustaining, consistent quality through the design, manufacture, distribution, installation, and servicing of products that comply with regulatory requirements and meet the need of worldwide medical device market, including expectations of our customers.

From a Quality and Regulatory perspective, our commitment is achieved through:

- Implementing and following a Quality Management System that meets the requirements of ISO, but not limited to, in order to comply with customer requirements;
- Continuous improvement in enhanced quality system by managing product risk, distribution risks and customer satisfaction;
- Commitment to meeting applicable national and international regulatory requirements;
- Reviewing quality objectives and implementing improvements;
- Personnel training and competences;
- Regulatory compliance and internal/external audits;
- Process effectiveness and efficiency.

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Ing. Marco Nassi – CEO ASG Superconductors S.p.A