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**STRATEGY FOR REGULATORY COMPLIANCE**

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# Purpose, scope, and users

The purpose of this document is to define the processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures.

Users of this document are the persons responsible for regulatory compliance, top management, and all other personnel responsible for achieving compliance of the medical device with all applicable requirements.

# Reference documents

* MDR 2017/745 articles 8, 10(9), 15, 19, and 25; Annex I, Annex IV, Annex IX, Annex X, Annex XI, and Annex XIII
* MDCG 2020-03 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR about devices covered by certificates according to MDD or AIMDD
* Procedure for Vigilance and Adverse Event Investigation and Reporting

# Person responsible for regulatory compliance

[Job title] appoints a person responsible for regulatory compliance (PRRC) with the qualifications specified in Article 15 of the MDR. The PRRC is, at a minimum, responsible for ensuring that:

* devices conform to the Quality Management System under which the devices are manufactured before such devices are released
* …

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