

Regulatory Compliance Certifications (RCCs)

RCC-MDR and RCC-IVDR Study Resources List

This list is intended to provide RCC candidates with a list of study resources they can consult for studying purposes. Exam items are designed to reflect practice and therefore there is no single set of study materials that should be considered exhaustive for studying purposes.

MDR: REGULATION (EU) 2017/745

IVDR: REGULATION (EU) 2017/746

Pay particular attention to the following sections:

- Article 15
- Article 10(4), 10(6), 10(9), 10(10) 10(13), 11(3) (AR), 19*, 20*, 87-91
- Annex II, III, XV Chapter II Section 4.1
- Note: Article 19 & 20 in the MDR are totally identical to Articles 17, 18 of the IVDR.

For a complete list of exam topics and their respective weights, see the Content Outlines located in the RCC Candidate Guide (RCC-MDR) and the RCC Candidate Guide (RCC-IVDR).

These designations do not qualify individuals to serve in the PRRC role, nor do they guarantee that an individual meets all the requirements necessary to practice as a qualified PRRC.

