MedTech Europe
from diagnosis to cure

Highlighting – Clinical Evidence Requirements

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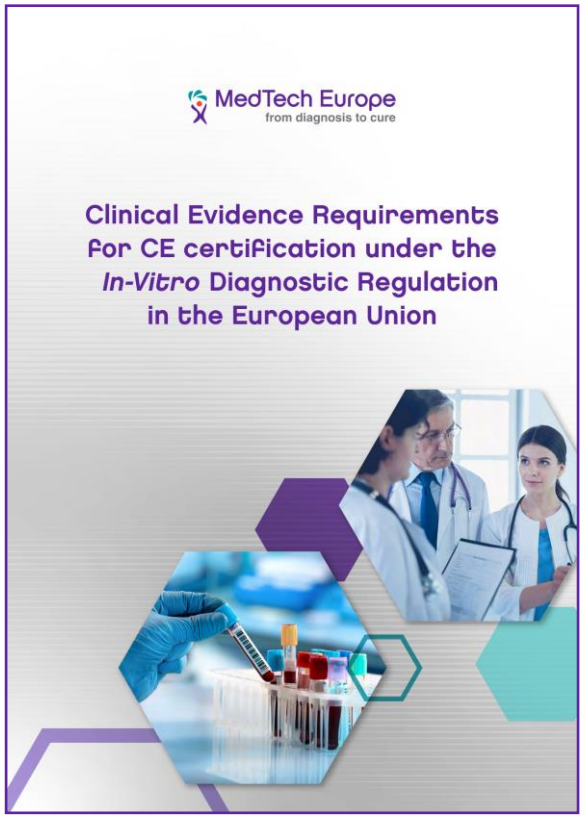
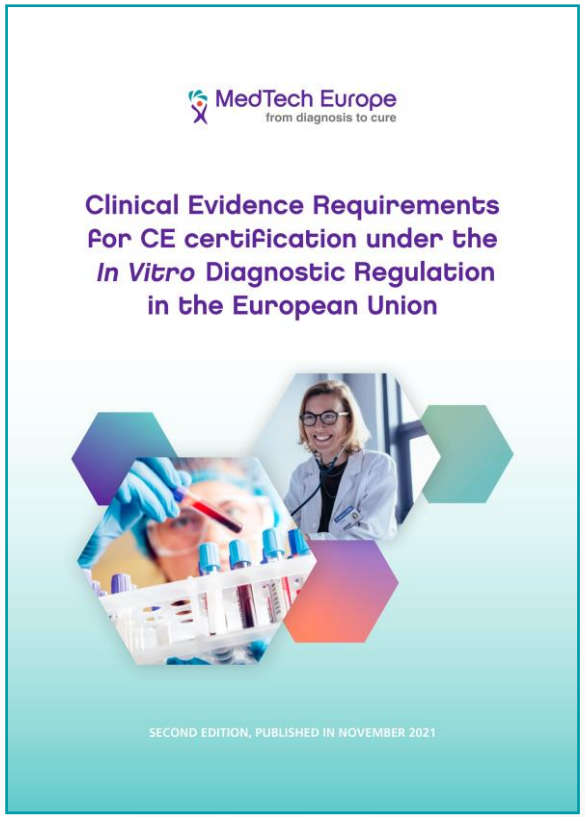
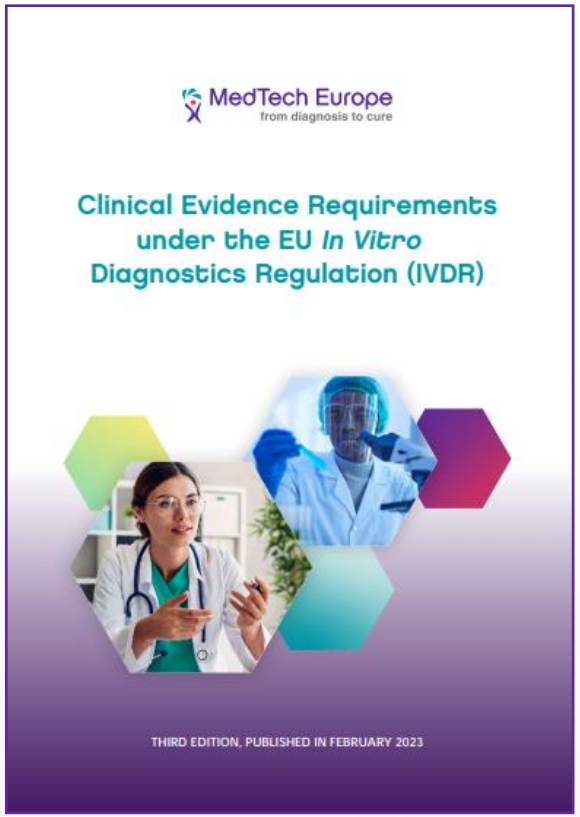
eBook Clinical Evidence Requirements under the EU *In Vitro* Diagnostic Regulation (IVDR)



First Edition
May 2020



Second Edition
November 2021



Third Edition
February 2023

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Chapter 1 ‘Intended Purpose / Use’

Chapter 2 Clinical Evidence

Chapter 3 State of the art (in medicine)

Chapter 4 Clinical Evidence Levels

Chapter 5 How to demonstrate evidence gained from ‘published/documented routine testing’

Chapter 6 Equivalence and similarity concepts in the IVDR

Chapter 7 Companion Diagnostics

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Chapter 8 Documentation of Performance Evaluation requirements

Chapter 9 Summary of safety and performance

Chapter 10 Post-market performance follow-up

Chapter 11 Benefit-Risk Requirements & Potential Approaches under the IVDR

Chapter 12 Near-Patient Testing (NPT)

Chapter 13 Use of Clinical Data from Outside the European Union