



BSI Training Academy

On-Demand Training

Awareness of the *In Vitro* Diagnostic Regulation
On-demand Training Course

February 2025





Essential information about the course

The In Vitro Diagnostic Regulation (IVDR), is a comprehensive set of European Union (EU) rules that govern the production, sale, and distribution of in vitro diagnostic devices. These devices play a crucial role in analyzing human samples, like blood or tissue, outside the body, providing essential data for medical diagnoses and treatment planning. This short course will focus on how the IVDR prioritizes safety, effectiveness, and the highest standards of public health within the EU.

Overall, this awareness course will help you understand what the IVD Regulation is, why it’s important, and how you can help your organization comply with this Regulation.

Our course agenda

This is an online, interactive eLearning course. Learning is self-study and you can progress at your own pace. You will have access to the course for 12 months.

On successful completion of your course, you’ll receive an internationally recognized BSI certificate

Course duration

30 minutes

Make sure the course is right for you

Who is this course for?
This course is ideal for all staff.

What will I learn?	What are the benefits?
<p>Upon completion of this course, you will be able to:</p> <ul style="list-style-type: none">• Explain how In Vitro Diagnostic Devices are regulated in Europe• Describe the commercial benefits of the CE Mark demonstrating conformity with the IVD Regulation• Suggest actions you can take to help with compliance to the IVD Regulation	<p>This course will help you:</p> <ul style="list-style-type: none">• Understand the regulatory framework for In Vitro Diagnostic Devices in Europe• Recognize the commercial advantages of obtaining the CE Mark as evidence of conformity with the IVD Regulation• Identify actionable steps you can take to ensure compliance with the IVD Regulation and how it can benefit you

Prerequisites

There are no formal prerequisites for this course.