

## CHAPTER 3

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# HOW TO USE THIS GUIDEBOOK

As mentioned in the welcome chapter, this book is not meant to be read from cover to cover, it is a set of tools and references that you can use to ensure you have met the requirements of the IVDR.

This book is broken down into chapters that represent different tools you can use. Colour coding is used to aid navigation and each section of the book has a different coloured bar on the outside margin of the page to allow quick referencing. The colour coding of each tool is represented by the coloured line under each tool description below.

The starting point for most users of this guidebook is chapter 4 – Manufacturers compliance guide and key players in the IVDR. This chapter identifies what a manufacturer needs to do to comply with the IVDR, and from there, what tools can be used as and when required.

The tools are set out below:

### **COMPLIANCE GUIDE:**

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The compliance guide is the starting point to aid compliance with the IVDR. It provides an overview to the requirements of the IVDR and helps a manufacturer build the documentation required to demonstrate compliance. This section also includes a list of questions that each economic operator should ask themselves.

### **DEVICE CLASSIFICATION:**

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This chapter lists the rules for classification and includes a flow for easy identification of device class and rulings.

### **PERFORMANCE EVALUATION:**

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This section provides some guidance on the requirements for performance evaluation and clinical evidence. It also includes a notified body inspired checklist. This is a very large subject, and this chapter gives a basic overview to help you get started.

### **CONFORMITY ASSESSMENT ROUTE ANNEXES:**

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This section provides a tabular view of the conformity assessment routes. It is a comparison tool that you can use to identify a preferred conformity route and the associated requirements.

### **QMS TABLES:**

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This chapter provides a set of useful tables that links the requirements of a Quality Management System to the requirements of the IVDR, this can be used to ensure that your QMS procedures meets the necessary requirements.

## **TIMELINES:**

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The IVDR has specific dates for implementation of different requirements. This chapter gives you visual timelines detailing the key dates and what is to be implemented before each date.

## **IVDR OVERVIEW ARTICLES:**

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This section provides an overview of the articles in the IVDR. It describes each article in simple terms, i.e. what it is about, a brief summary and also the conformity evidence required. A map is also included to identify any links with other articles and annexes.

## **IVDR OVERVIEW ANNEXES:**

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This chapter provides an overview of the annexes in the IVDR. It describes each annex in simple terms as is done in the articles chapter. Annex I includes a checklist for the GSPRs and Annex III contains a PMS checklist.

## **INDEXES & LOOK UPS:**

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References have been collated and listed to allow review for further information. This list includes acronyms, delegating acts, other directives and regulations and a who's who in the IVDR.

## **MDCG GUIDANCE:**

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This chapter contains a table with the reference, title, publication date, relevant articles/annexes and the operator/user the guidance is intended for (only those relevant to the IVDR).