IN VITRO DIAGNOSTIC MEDICAL DEVICES

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LAW AND PRACTICE IN FIVE EU MEMBER STATES: FRANCE, GERMANY, ITALY, SPAIN AND THE UNITED KINGDOM

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Editors' Note

The authors are grateful to all those who contributed to their work in various ways, in particular the European Commission, the European Diagnostic Manufacturers Association (EDMA), the national associations of manufacturers of IVDMDs and officials within the national health authorities. Responsibility for the national reports remains with the authors. The authors have taken care to verify the contents of this book and intend it to be a useful practical guide, but nonetheless recommend that readers, bearing in mind the purpose for which the reports were written, seek specialist advice before applying the information to the facts of a particular case, especially in view of the possibility of subsequent changes in law or practice.

The Editors

Preface

The forerunner of this study was a five-nation report prepared at the request of the European Commission in January 1991. Its purpose was to set out the existing laws regulating the development, production, distribution and use of *in vitro* diagnostic medical devices (IVDMDs) in the United Kingdom, Germany, France, Italy and Spain. Each national section of the report was to have the same structure and cover the same ground in order that comparisons of the national laws could readily be made. The result was an interim report submitted to the European Community Study Group in June 1991.

The interim report was reviewed by Directorate-General III. It was subsequently expanded and modified as the result of further work by the contributors and discussions of the report at a meeting of the European Commission Working Group of Experts on IVDMDs and at the subsequent European Diagnostic Manufacturers Association conference which took place in October 1991. The final report was submitted to the European Commission in June 1992. The study has played a significant part in shaping the Commission's Working Papers for a future Directive on IVDMDs which will be published in 1994, the aim of which is to harmonize the laws of the European Union in this area. Until the Directive is fully implemented, it will continue to be necessary to refer to the laws of the individual countries. This study is the only comprehensive exposition of the laws of the five countries relating to IVDMDs available, and is the most convenient means of comparing those laws. As such, it will be a useful guide to all IVDMD manufacturers interested in the European market.

March 1994

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Director-General
of the European Diagnostic
Manufacturers Association