The Author	3
List of Abbreviations	17
General Introduction	19
§1. MEDICAL LAW AND HEALTH LAW	19
§2. MEDICAL LAW AND HEALTH LAW IN THE EU	20
§3. EUROPEAN UNION HEALTH LAW OR EU HEALTH LAWI. EU Biomedical LawII. EU Health Law	20 21 22
§4. THE CONTENTS OF EU HEALTH LAW IN THIS MONOGRAPH	24
Part I. Definitions	25
Chapter 1. Definition of Healthcare, Medical Care and Health Services in EU Law	25
 §1. ARE HEALTHCARE AND MEDICAL CARE SYNONYMOUS IN EU HEALTH LAW? I. Healthcare II. Medical Care 	25 25 25
§2. HEALTH SERVICESI. Services to Assess, Maintain or Restore the State of Health of a	30
 Patient II. Prescription, Dispensation and Provision of Medicinal Products and Medical Devices A. Medicinal Product B. Medical Device C. Health Technology 	30 33 35 35 36
III. Freedom of Member States to Determine Health ServicesA. The Selling of Contact Lenses Is Not a Health ServiceB. An Optician's Shop Is Not a Health ServiceC. Pharmaceutical Activities Are Health Services	37 37 38 39

5

 Health Services Include Pharmaceutical Services All Pharmaceutical Services Are Health Services 	39 39
D. Pharmacies Are Health Services	40
E. Dental Services Are Health Services	41
F. Day and Night Reception Centres for the Elderly	41
G. The Administration of Medication by a Nurse	45
H. Sports or Fitness Clubs Are Not Health Services	46
Chapter 2. The Concept of Health Professionals in EU Law	47
§1. NOT LIMITED TO REGULATED PROFESSIONS	47
§2. MEDICAL, ALLIED AND PHARMACEUTICAL PROFESSIONS	47
§3. LARGE MARGIN OF DISCRETION FOR MEMBER STATES TO DETERMINE	
A MEDICAL OR A PARAMEDICAL PROFESSION	48
I. Opticians	48
II. Physiotherapy	49
A. General Observation	49
B. Physiotherapy and Disturbance Field Diagnostics (Method of	50
Treatment Alternative to Traditional Medicine)	50 53
C. Physiotherapy and Osteopathy (Non-conventional Therapy)	55
D. Psychotherapy	55
Part II. Access and Pursuit of the Healthcare Professions	59
Chapter 1. The Mutual Recognition of Professional	
Qualifications	59
§1. Purpose	59
§2. Effects of Recognition	60
§3. The European Professional Card (EPC)	60
I. Limited Implementation of EPC for the Healthcare Professions	60
II. Application for an EPC and Creation of an IMI File	61
III. Processing and Access to Data Regarding the EPC (Prohibition	
and Restriction of Activities)	61
IV. Verification of the Authenticity and Validity of an EPC by Third	
Parties	62
§4. Partial Access	62
§5. Proportionality Principle and Proportionality Test	65

Chapter 2. Free Provision of Services	68
 §1. PRINCIPLE OF FREE PROVISION OF SERVICES No Restriction of Free Provision of Services Subject to Professional Rules Directly Linked to Profession 	68 68 al
Qualifications III. Exemption from Authorisation by, Registration with or	68
Membership of a Professional Organisation	70
§2. DECLARATION TO BE MADE IN ADVANCE	70
§3. Use of the Professional Title of the Member State of Establishment	71
§4. PRIOR CHECK OF PROFESSIONAL QUALIFICATIONS	72
§5. Administrative Cooperation in the Event of Justified Do or Complaints	OUBTS 73
§6. INFORMATION TO BE GIVEN TO THE RECIPIENTS OF THE SERVICE	E 73
Chapter 3. Freedom of Establishment Through Recognitio on the Basis of Coordination of Minimum	n
Training Conditions	74
 §1. DOCTORS OF MEDICINE Principle of Automatic Recognition (Admission to) Basic Medical Training (Admission to) Specialist Medical Training Types of Specialist Medical Training Specific Training in General Medical Practice VI. Pursuit of the Professional Activities of General Practitioner 	74 74 75 76 76 76 77
§2. NURSES RESPONSIBLE FOR GENERAL CAREI. Principle of Automatic RecognitionII. Training of Nurses Responsible for General Care	77 77 78
 §3. DENTAL PRACTITIONERS Principle of Automatic Recognition Basic Dental Training Specialist Dental Training Pursuit of the Professional Activities of Dental Practitioners 	80 80 80 81 82
§4. MIDWIVES I. The Training of Midwives	82 82

II. Procedures for the Automatic Recognition of Evidence of Formal Qualifications as a MidwifeIII. Pursuit of the Professional Activities of a Midwife	83 84
 §5. PHARMACISTS Principle of Automatic Recognition Training as a Pharmacist Pursuit of the Professional Activities of a Pharmacist 	84 84 85 86
Chapter 4. Freedom of Establishment Through the General System for the Recognition of Evidence of Training	87
Chapter 5. Common Provision on Establishment: Use of Professional Titles	88
Chapter 6. Detailed Rules for Pursuing the Profession	89
§1. KNOWLEDGE OF LANGUAGES	89
§2. Use of Academic Titles	91
§3. Approval by Health Insurance Funds for Doctors and Dental Practitioners	91
Chapter 7. Exchange of Information Regarding Disciplinary Action and Criminal Sanctions and Alert Mechanism	92
§1. Exchange of Information Regarding Disciplinary Action and Criminal Sanctions	92
§2. Alert Mechanism	92
Part III. The Practice of the Healthcare Professions	97
Chapter 1. The (Illegal) Practice of Medical Acts	97
§1. Osteopathy	97
§2. Eye Examinations	98
Chapter 2. Professional Rules of Conduct	100
§1. SINGLE-PRACTICE RULE	100

8

 §2. ADVERTISING FOR MEDICAL SERVICES I. Legal Prohibition of Advertising II. Prohibition by National Disciplinary Rules 	103 103 106
§3. MEDICAL FEES	107
Part IV. Patients' Rights in EU Law	111
Chapter 1. Who Is a Patient in EU Law?	111
Chapter 2. Patients' Rights in EU Law in General	114
§1. INTRODUCTION	114
 §2. PATIENTS' RIGHTS IN THE CHARTER OF FUNDAMENTAL RIGHTS OF THE EU Introduction Free and Informed Consent (Article 3.1. and 3.2a Charter) Right to Privacy and Right to Data Protection Right of Access to Preventive Healthcare and to Benefit from Medical Treatment 	115 115 115 117 118
 §3. PATIENTS' RIGHTS IN SECONDARY EU LAW Right to Report Suspected Side Effects of Medicinal Products Right to Report Suspected Adverse Reactions of Medicinal Products III. Right to Receive Information Regarding Implantable Medical Devices on an Implant Card 	119 119 119 120
 §4. PATIENTS' RIGHTS IN EU SOFT LAW DOCUMENTS Documents Approved by the European Parliament European Charter on the Rights of the Patient European Charter for Children in Hospital II. The European Charter of Patients' Rights Introductory Remarks European Charter of Patients' Rights: Part One – 	121 121 121 122 124 124
Fundamental Rights C. European Charter of Patients' Rights: Part Two – Fourteen	125
 Patients' Rights Article 1. Right to Preventive Measures Article 2. Right of Access Article 3. Right to Information Article 4. Right to Consent Article 5. Right to Free Choice Article 6. Right to Privacy and Confidentiality Article 7. Right to Respect of Patients' Time 	125 126 126 126 127 127 127 127

	8.	Article 8. Right to the Observance of Quality Standards	128
	9.	Article 9. Right to Safety	128
	10.	Article 10. Right to Innovation	128
	11.	Article 11. Right to Avoid Unnecessary Suffering and	
		Pain	129
	12.	Article 12. Right to Personalised Treatment	129
	13.	Article 13. Right to Complain	129
	14.	Article 14. Right to Compensation	129
	D. Eu	ropean Charter of Patients' Rights: Part Three - Rights of	
		tive Citizenship	129
	E. Eu	ropean Charter of Patients' Rights: Part Four - Guidelines	
	for	Implementing the Charter	130
III.	Opinio	n on 'Patients' Rights' of the European Economic and	
	Social	Committee	130
	A. Int	roduction	130
	B. Rig	ghts of Patients	132
	1.	Right to Information	132
	2.	Right to Free and Informed Consent	133
	3.	Right to Dignity	133
	4.	Other Individual Rights	133
	C. Re	commendations for Implementing Patients' Rights	134
	D. To	wards an Affirmation of Collective Rights	134
IV.	Patient	's Rights in the Interinstitutional Proclamation on the	
	Europe	an Pillar of Social Rights	134
Chapter	3. Pa	tients' Rights and the Cross-Border Healthcare	
1		rective	136
§1. The	PATIEN	NTS' RIGHT TO HEALTHCARE	136
•		tients' Right to Healthcare	136
		e Patients' Right to Receive Healthcare in Another	
		ember State	136
	B. Th	e Special Case of Access to Organs for Transplantation	137
§2. PAT	IENTS'	RIGHTS TO INFORMATION	138
I.	The Pa	tients' Right to Information with Regard to	
	Reimb	ursement	138
II.	The Pa	tients' Right to Information Regarding the Nature of	
		care and the Circumstances in Which It Is Provided	138
	A. Int	formation on Request of the Patient by the NCP of the	
		ember State of Treatment	138
	1.	Relevant Information on the Standards and Guidelines	
		on Quality of Safety	139
	2.	Information on Supervision and Assessment of	
		Healthcare Providers	140
	3.	Information on the Accessibility of Hospitals for Persons	
		with Disabilities	140

			 Information on a Specific Provider's Right to Provide Services 	140
			 Information on Patients' Rights, Complaints Procedures and Mechanisms for Seeking Remedies 	141
			6. Information on the Legal and Administrative Options Available to Settle Disputes, Including in the Event of	
			Harm Arising from Cross-Border Healthcare	141
			7. Information on NCP in Other Member States	142
			8. Language in Which Information Is Provided by NCP	142
		Β.	Information to Be Provided by Healthcare Providers	143
§3.	THE	PA	TIENTS' RIGHT TO HEALTHCARE THAT IS SAFE AND OF GOOD	
	QUA			147
	I.		althcare Corresponding with National and Union Quality and	
			ety Standards	147
	II.	Qu A.	ality and Safety as a Justification for Prior Authorisation The Treatment Presents a Particular Risk for the Patient or	148
			the Population	148
		B.		
			Safety of the Care Provided by a Healthcare Provider	149
	III.	-	ality and Safety as a Justification to Refuse a Prior	
			thorisation	150
			The Patient Will Be Exposed to a Safety Risk	151
		B.	The General Public Will Be Exposed to a Substantial Safety Hazard	151
		C.	Concerns Regarding the Quality and Safety of the Care	
			Provided by a Healthcare Provider	151
§4.	THE	PA	TIENTS' RIGHT TO COMPLAIN	151
§5.	THE	PA	TIENTS' RIGHT TO RECEIVE COMPENSATION OF DAMAGES	152
§6.	THE	PA	TIENTS' RIGHT TO RESPECT OF PRIVATE LIFE	152
§7.	THE	PA	tients' Right to a Medical Record and Access to It	153
§8.			TIENTS' RIGHT TO RECOGNITION OF A PRESCRIPTION FOR A NAL PRODUCT	154
Part	V.		The Physician-Patient Relationship in Specific Terms in EU Law	155
Cha	nter	1	Clinical Trials on Medicinal Products for Human	
Jina	ptor	1.	Use	155
§1.	INTR	OD	UCTION	155
				11

§2.	FIEL	DO	F APPLICATION OF THE CLINICAL TRIALS REGULATION	156
§3.			otection of Subjects in Clinical Trials	157
			or Authorisation	157
	II.	Ger	neral Provisions for the Protection of Subjects	161
			General Principle	161
		Β.	Proportionality Requirement (Balance Benefits-Risks)	161
		C.	Informed Consent	162
			1. Express Informed Consent as a Rule	162
			2. Implicit Informed Consent for Cluster Trials	164
			3. Withdrawal of Informed Consent	165
		D.	Respect for the Rights to Physical and Mental Integrity, to	
			Privacy and to Data Protection	165
		E.	As Little Pain, Discomfort, Fear and Any Other Foreseeable	
			Risk	166
		F.	Medical Care under the Responsibility of an Appropriately	
			Qualified Medical Doctor/Dental Practitioner	166
		G.	No Undue Influence	166
		Η.	Protection of Subjects During the Clinical Trial	166
			1. Conduct in Accordance with the Protocol and Good	
			Clinical Practice Principles	166
			2. Adequate Monitoring of the Conduct of the Clinical	
			Trial	166
			3. Qualified Investigator	167
			4. Suitable Facilities	167
			5. Notification of Serious Breaches of Safety and Rights of	
			a Subject	167
			6. No Costs to Be Borne by the Subject	167
		I.	Damage Compensation	167
		J.	Summary of the Results of the Clinical Trial Within One	
			Year	168
	III.	Cli	nical Trials on Incapacitated Subjects	168
		Α.	Incapacitated Subject	168
		Β.	Informed Consent of the Legally Designated Representative	169
			1. Basic Rule	169
			2. Legally Designated Representative	169
			3. Participation and Signature of the Subject	169
		C.	Information to Be Provided to the Incapacitated Person	169
		D.	Respect for the Explicit Wish to Refuse or Withdraw	
			Consent	170
		E.	No Incentives or Financial Inducements	170
		F.	Clinical Trial Is Essential and No Alternative	170
		G.	Directly Related to the Medical Condition of the Subject	170
		H.	A Direct Benefit for the Subject or	170

	I Some Benefit for the Population Represented by the	
	Subject and Directly Related to the Life-Threatening or	
	Debilitating Medical Condition from Which the Subject	
	Suffers	171
	J. Ethical Assessment on the Basis of Expertise in the Relevant	
	Disease	172
IV.	Clinical Trials on Minors	172
	A. Basic Rule	172
	B. Informed Consent	172
	1. Informed Consent of the Legally Designated	
	Representative	172
	2. Participation of the Minor	173
	3. Assent of the Minor	173
	4. Informed Consent of the Minor When He Reaches the	175
	Age of Legal Competence	173
	C. Information to Be Provided to the Minor	173
	D. Explicit Wish to Refuse Is Respected	173
	E. No Incentives or Financial Inducements	173
	F. A Medical Condition That Only Occurs in Minors or	174
	G Essential to Validate Alternatives	174
	H. Directly Related to the Medical Condition of the Minor or	
	No Alternative but Minors	174
	I. A Direct Benefit for the Minor or	174
	J Some Benefit for the Population Represented by the	
	Minor	174
	K. Ethical Assessment on the Basis of Paediatric Expertise	175
V.	Clinical Trials on Pregnant or Breastfeeding Women	175
VI.	Clinical Trials on Other Vulnerable Subjects	175
VII.	Clinical Trials in Emergency Situations	176
hapter	2. Clinical Investigations on Medical Devices	178
§1. FIEI	LD OF APPLICATION	178
J		
§2. CON	NDITIONS TO CONDUCT A CLINICAL INVESTIGATION	178
-	Generally Applicable Conditions	178
	A. Authorisation	179
	B. No Negative Opinion of an Ethics Committee	179
	C. Sponsor Established in the EU	180
	D. Proportionality Requirement (Balance Benefits-Risks)	180
	E. Informed Consent of the Subject	180
	F. Contact Details for Further Information	182
	G. Respect for the Rights to Physical and Mental Integrity, to	
	Privacy and to Data Protection	182
	H. As Little Pain, Discomfort, Fear and Any Other Foreseeable	
	Risk	182

I. Medical Care under the Responsibility of an Appropriately	
Qualified Medical Doctor/Dental Practitioner	182
J. No Undue Influence	182
K. The Investigational Device Conforms to the Applicable	
General Safety and Performance Requirements	182
L. Carried Out in Accordance with Recognised Ethical	
Principles	183
M. Qualified Investigator and Other Personnel	183
N. Suitable Facilities	183
O. Damage Compensation	183
II. Clinical Investigations on Incapacitated Subjects	183
III. Clinical Investigations on Minors	184
IV. Clinical Investigations on Pregnant or Breastfeeding Woman	185
V. Clinical Investigations on Other Vulnerable Subjects	185
VI. Clinical Investigations in Emergency Situations	186
(II) Chine and Congations in Zhiergeney Steamons	
Chapter 3. Performance Studies on In Vitro Diagnostic	
Medical Devices	188
Wiedlear Devices	100
§1. FIELD OF APPLICATION	188
SI. HELD OF AITLICATION	100
§2. Conditions to Conduct a Performance Study	188
I. General Requirements Regarding Performance Studies	188
II. Additional Requirements for Certain (Invasive) Performance	100
Studies	189
	191
III. Performance Studies on Incapacitated Subjects	191
IV. Performance Studies on Minors	
V. Performance Studies on Pregnant or Breastfeeding Women	192 192
VI. Performance Studies on Other Vulnerable Subjects	
VII. Performance Studies in Emergency Situations	192
Chapter 4 Non interventional Post Authorisation Safety	
Chapter 4. Non-interventional Post-Authorisation Safety	100
Studies	193
Charter 5 Har of Harris Eachman for Democra of Scientific	
Chapter 5. Use of Human Embryos for Purposes of Scientific	
Research	194
Chapter 6. Genetic Testing	195
Chapter 7. The Processing of Data Concerning Health and	
Genetic Data	197
§1. FIELD OF APPLICATION	197
§2. PROCESSING OF DATA CONCERNING HEALTH AND GENETIC DATA	198
I. Prohibition of Processing of Data Concerning Health and Genetic	;
Data	198

	II.	Derogation from the Prohibition on Processing of Data	
	11.	Regarding Health and Genetic Data	199
		A. Compliance with the Principles Relating to Processing of	
		Personal Data	199
		B. One of the Following Justifications Applies	199
			1))
		9	199
		Responsibility Has Given Explicit Consent	199
		2. Necessity to Protect the Vital Interests of the Data	000
		Subject or of Another Natural Person	200
		3. Necessary for Reasons of Substantial Public Interest	201
		4. Necessary for Health-Related Purposes	201
		5. Necessary for Reasons of Public Interest in the Area of	
		Public Health	202
		C. Comply with Member States Further Conditions	203
	III.	Rights of the Data Subject	203
		A. The Right to the Protection of Personal Data	203
		B. Information to Be Provided Where Personal Data Are	
		Collected from the Data Subject	203
		C. The Right of Access by the Data Subject	204
		D. Right to Rectification	205
		E. Restricted Right to Erasure of Personal Data Regarding	
			205
			206
		G. Restricted Right to Portability of Data Regarding Health or	
			207
		H. Right Not to be Subject to Automated Individual Decision-	207
		e .	208
		I. Right to Transparent Information and Communication	200
		•	208
			200
		J. Right to Lodge a Complaint and to an Effective Judicial	209
			209
		0	
	13.7		210
		0 5	210
		Data Protection by Design and by Default	211
		5	211
		1	212
	VIII.	Designation of a Data Protection Officer When Data Regarding	
		Health or Genetic Data Are Processed on a Large Scale	212
§3.		ENTIFIC RESEARCH WITH DATA CONCERNING HEALTH OR	
			213
			213
		,	214
	III.	Appropriate Safeguards for the Rights and Freedoms of the Data	
		Subject	215
	IV.	Explicit Consent	215

V. Processing for Research Purposes Is in the Public Interest or Has a Legitimate Interest	216
Chapter 8. Transplantation of Organs	217
Chapter 9. Clinical Use of Tissues and Cells of Human Origin for Human Application	220
Chapter 10. Rights of the Medical Examinee	221
§1. RIGHTS OF THE LIVING ORGAN DONOR	221
§2. RIGHTS OF THE LIVING DONOR OF TISSUE AND CELLS	223
§3. RIGHTS OF THE DONOR OF BLOOD	224
Part VI. Beginning and End of Life Issues in EU Law	227
Chapter 1. Beginning of Life	227
§1. DEFINITION OF THE LEGAL TERM 'PERSON' OR 'INDIVIDUAL'	227
§2. PROTECTION OF THE HUMAN BODY	227
§3. DEFINITION AND PROTECTION OF THE HUMAN EMBRYO	228
§4. IN VITRO FERTILISATION AND THE BEGINNING OF A PREGNANCY	230
§5. GAMETES DONATION FOR REPRODUCTION	232
§6. VOLUNTARY TERMINATION OF PREGNANCY	232
Chapter 2. End of Life	235
§1. The Deceased Organ Donor	235
§2. THE DECEASED CELLS AND TISSUE DONOR	235
§3. Advance Directives	236
§4. Euthanasia	236
Selected Bibliography	239
Index	247

16