

Directive 2002/98/EC of the European Parliament and of the Council  
of 27 January 2003 setting standards of quality and safety for the  
collection, testing, processing, storage and distribution of human  
blood and blood components and amending Directive 2001/83/EC

CHAPTER I

GENERAL PROVISIONS

- Article 1 Objectives
- Article 2 Scope
- Article 3 Definitions
- Article 4 Implementation

CHAPTER II

OBLIGATIONS ON MEMBER STATES AUTHORITIES

- Article 5 Designation, authorisation, accreditation or licensing of blood establishments
- Article 6 Hospital blood banks
- Article 7 Provisions for existing establishments
- Article 8 Inspection and control measures

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

- Article 9 Responsible person
- Article 10 Personnel

CHAPTER IV

QUALITY MANAGEMENT

- Article 11 Quality system for blood establishments
- Article 12 Documentation
- Article 13 Record keeping

CHAPTER V

HAEMOVIGILANCE

- Article 14 Traceability
- Article 15 Notification of serious adverse events and reactions

## CHAPTER VI

### PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

- Article 16 Provision of information to prospective donors
- Article 17 Information required from donors
- Article 18 Eligibility of donors
- Article 19 Examination of donors
- Article 20 Voluntary and unpaid blood donation
- Article 21 Testing of donations
- Article 22 Storage, transport and distribution conditions
- Article 23 Quality and safety requirements for blood and blood components

## CHAPTER VII

### DATA PROTECTION

- Article 24 Data protection and confidentiality

## CHAPTER VIII

### EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

- Article 25 Information exchange
- Article 26 Reports
- Article 27 Penalties

## CHAPTER IX

### COMMITTEES

- Article 28 Committee procedure
- Article 29 Technical requirements and their adaptation to technical and scientific progress
- Article 30 Consultation of scientific committee(s)

## CHAPTER X

### FINAL PROVISIONS

- Article 31 Amendment of Directive 2001/83/EC
- Article 32 Transposition
- Article 33 Entry into force
- Article 34 Addressees

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## ANNEX I

### INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES

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## OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING IN ACCORDANCE WITH ARTICLE 5(2)

Part A:

General information:

Part B:

A description of the quality system, to include:

### ANNEX II

#### REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

This annual report will include:

total number of donors who give blood and blood components...

### ANNEX III

#### LABELLING REQUIREMENTS

The label on the component must contain the following information:...

the official name of the component the volume or weight...

### ANNEX IV

#### BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and...  
ABO Group (not required for plasma intended only for  
fractionation)...

Additional tests may be required for specific components or  
donors...

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- (1) OJ C 154 E, 29.5.2001, p. 141 and OJ C 75 E, 26.3.2002, p. 104.
- (2) OJ C 221, 7.8.2001, p. 106.
- (3) OJ C 19, 22.1.2002, p. 6.
- (4) Opinion of the European Parliament of 6 September 2001 (OJ C 72 E, 21.3.2002, p. 289), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European Parliament of 12 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.
- (5) OJ L 311, 28.11.2001, p. 67.
- (6) OJ C 164, 30.6.1995, p. 1.
- (7) OJ C 374, 11.12.1996, p. 1.
- (8) OJ C 268, 4.10.1993, p. 29.
- (9) OJ C 329, 6.12.1993, p. 268.
- (10) OJ C 249, 25.9.1995, p. 231.
- (11) OJ C 141, 13.5.1996, p. 131.
- (12) OJ L 281, 23.11.1995, p. 31.
- (13) OJ L 203, 21.7.1998, p. 14.
- (14) OJ L 184, 17.7.1999, p. 23.