

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 2*

#### **Scope**

1 This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.

Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing.

2 This Directive shall not apply to:

- a tissues and cells used as an autologous graft within the same surgical procedure;
- b blood and blood components as defined by Directive 2002/98/EC;
- c organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.