

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 III

DONOR SELECTION AND EVALUATION

Article 15

Selection, evaluation and procurement

- 1 The activities related to tissue procurement shall be carried out in such a way as to ensure that donor evaluation and selection is carried out in accordance with the requirements referred to in Article 28(d) and (e) and that the tissues and cells are procured, packaged and transported in accordance with the requirements referred to in Article 28(f).
- 2 In the case of an autologous donation, the suitability criteria shall be established in accordance with the requirements referred to in Article 28(d).
- 3 The results of the donor evaluation and testing procedures shall be documented and any major anomalies shall be reported in accordance with the requirements referred to in the Annex.
- 4 The competent authority or authorities shall ensure that all activities related to tissue procurement are carried out in accordance with the requirements referred to in Article 28(f).