

Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010
on standards of quality and safety of human organs intended for transplantation

CHAPTER II

THE QUALITY AND SAFETY OF ORGANS

Article 10

Traceability

- 1 Member States shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.
- 2 Member States shall ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such a system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national provisions, as referred to in Article 16.
- 3 Member States shall ensure that:
 - a the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex, in accordance with the framework for quality and safety;
 - b data required for full traceability is kept for a minimum of 30 years after donation. Such data may be stored in electronic form.
- 4 Where organs are exchanged between Member States, those Member States shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission pursuant to Article 29.