Objectives

The primary aim is to support the traceability of human tissues and cells that are applied to patients in the European Union.

EUROCET128 CONSORTIUM

Funded by the European Commission

EUROCET128

BUILDING REFERENCE COMPENDIA FOR THE APPLICATION OF A SINGLE EUROPEAN CODING SYSTEM FOR TISSUES AND CELLS

21 December 2011 – 20 June 2014

Tissues and cells such as corneas, heart valves, cord blood or bone marrow are used in transplant procedures to repair or replace damaged tissue or cells. Fertility treatment frequently involves the manipulation and application of gametes, such as sperm or eggs, or embryos. In these fields, it is essential to maintain traceability so that the cells or tissues can always be linked back to the original centre where they were collected and, indeed to their original human origin.
Traceability of these substances across the EU will be improved by the implementation of a single European Coding System, summarised as follows:

DONATION IDENTIFICATION

ISO country	TE code	Unique donation number (local/national)
2 characters	6 characters (alpha-numeric)	13 characters (alpha-numeric)

PRODUCT IDENTIFICATION

Product code	Split number	Expiry date
1 symbol + 7 characters (alpha-numeric)	3 characters (alpha-numeric)	8 characters (alpha-numeric)

The implementation will be supported through the construction of two official public lists. The first, called the Tissue Establishment Compendium, will be a list of authorized centres that receive, test, process, store and distribute tissues or cells (including gametes and embryos) for human application, and the second, called the Product Compendium, will be a list of types of tissues and cells with agreed descriptions. All authorised EU tissue and cell centres will be allocated agreed EU codes and all tissues and cells will be coded using either an existing coding system, or an EU Generic code. An electronic code translator will allow those who receivetissues or cells for human use to immediately establish both the origin and the EU description of the material. The completed lists, codes and code translator will be provided to the European Commission for future maintenance.

ITALIAN NATIONAL TRANSPLANT CENTRE

Centro Nazionale Trapianti

EUROCET

www.eurocet.org

ARTMAN TECHNOLOGIES

www.artman.eu

ICCBBA

ISBT 128

www.iccbba.org

For further info:

WWW.EUROCET128.EU

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Tissue Establishment Compendium

The tissue establishment compendium provides a publicly accessible list of authorised tissue establishments in the European Union (EU) with their relevant identifying codes and minimum data set.

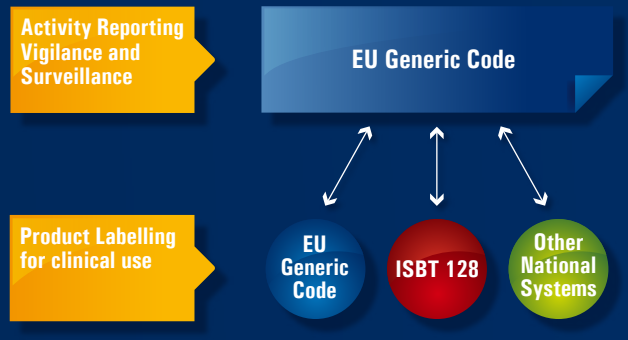
The compendium is constructed on the Eurocet (European network of the competent authorities for tissues and cells) project which was initially funded by DG INFSO.
Eurocet collects from EU tissue and cell Competent Authorities information on tissue establishments and tissue and cell procurement and human application activities. The consortium will develop a procedure for continuous updating of the authorised list with details related to specific tissue and cells types and specific activities authorised. Tissue establishment codes will be allocated in line with the Single European Coding System.

Product Compendium

The product compendium provides a means of harmonizing product descriptions and coding throughout the EU.

For the traceability and labelling of products for clinical use it provides a high level generic coding system but also supports the use of the international standard ISBT 128 and existing national systems.

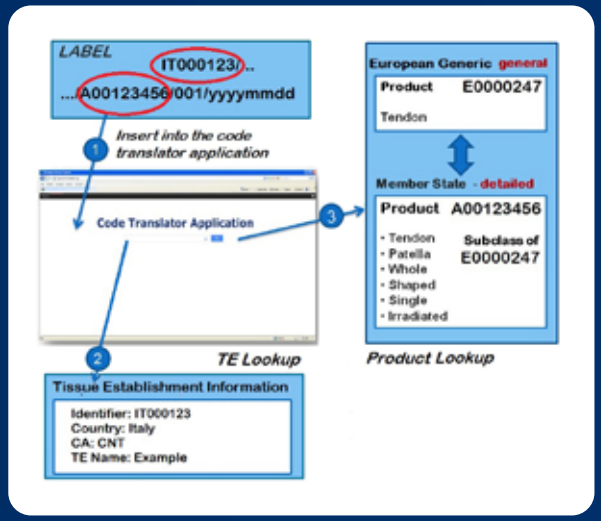
Within the compendium these systems are mapped to their corresponding European Generic Code thus providing a consistent means of categorising products for activity gathering and vigilance and surveillance purposes.



This two tier approach ensures consistency of coding at the European level, whilst supporting the clinical identification needs of Member States.

The Code Translator

The Code Translator provides an online application to translate alphanumeric codes to textual information as well as to translate textual information to alpha-numeric codes.



The code-translator application has the two compendia under appropriate security controls.

Tissue and cell professionals, clinical users and regulators will be able to enter the application and insert the code for a product or tissue establishment and convert it to the EU code structure and associated data and descriptions or vice versa.

The application will be installed in an EU location and will be provided together with guidance and manuals for users.