

Federal agency for medicines and health products

INTERNATIONAL CELL PRODUCT LABELING REGULATIONS/ SEC

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National JACIE meeting day

Brussels 28/10/2016

Coding legislation (1)

Directive 2004/23/EC, Article 25. Coding of information

2. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells.

Commission Directive 2006/86/EC, Article 10. European coding system

1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate at least the information set out in Annex VII.

2. Paragraph 1 shall not apply to partner donation of reproductive cells.

Annex VII. Information contained in the European coding system.

1. Donation identification (unique ID number, identification TE)
2. Product identification (product code, split number, expiry date)



Coding legislation (2)

COMMISSION DIRECTIVE (EU) 2015/565

of 8 April 2015

amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

“Single European Code” or **“SEC”** means the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence.

“EU Coding Platform” : IT platform hosted by the Commission containing EU Tissue Establishment Compendium and EU Tissue and Cell Product Compendium:

- **“EU Tissue Establishment Compendium”**: register of all authorised TEs in EU (updated by Member States' CAs).
- **“EU Tissue and Cell Product Compendium”** register of all types of T&Cs distributed in EU for human application and the respective product codes under the three permitted coding systems (EUTC*, ISBT128 and Eurocode) (updated by EC).

*EUTC: coding system for TC developed by EU consisting of a register of all types (and codes) of TC circulating in EU, = high level system.



Structure and format of SEC

DONATION IDENTIFICATION SEQUENCE (DIS)			PRODUCT IDENTIFICATION SEQUENCE			
TE code		Unique Donation number	Product code		Split number	Expiry date
ISO country identifier	TE number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character E = EUTC A = ISBT128 B = Eurocode	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters

EC SANTE, 2016

SEC	BE	FAMHP TE number	FREE	E/A or B	Acc. to choice E/A or B	000*	YYYYMM DD**
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***if no split: 000; **if no expiry date: 0000/00/00**



Example of label (import of HPC, marrow)

ISBT 128

EUTC

OR

SEC	BE060001G99914123456	AS12894B00020140301
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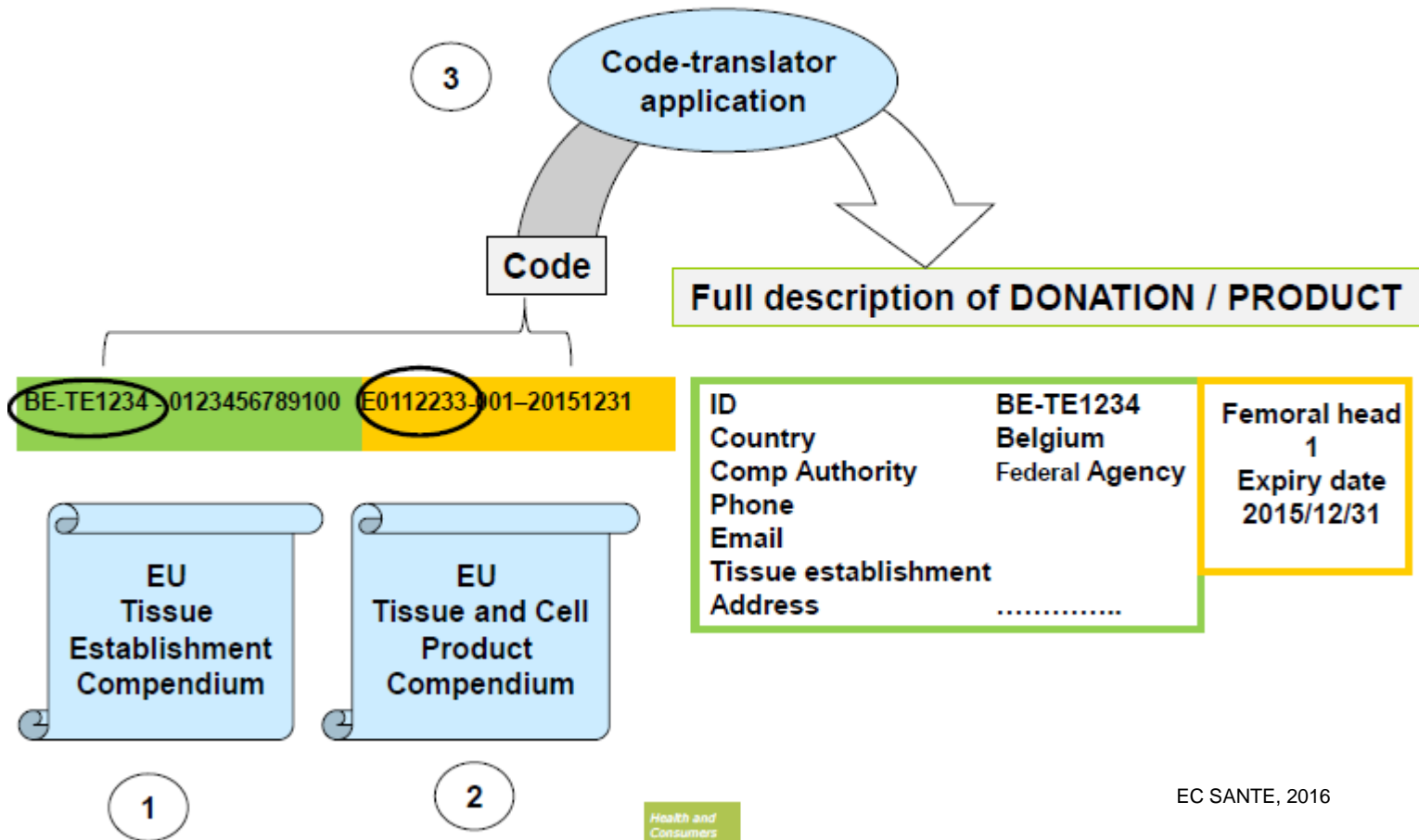
SEC	BE	060001	G99914123456	A	S12894B0	000	20140301
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SEC	BE06000100000000000004	E000000700020140301
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SEC	BE	060001	00000000000004	E	0000078	000	20140301
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Tools for SEC implementation



Health and Consumers

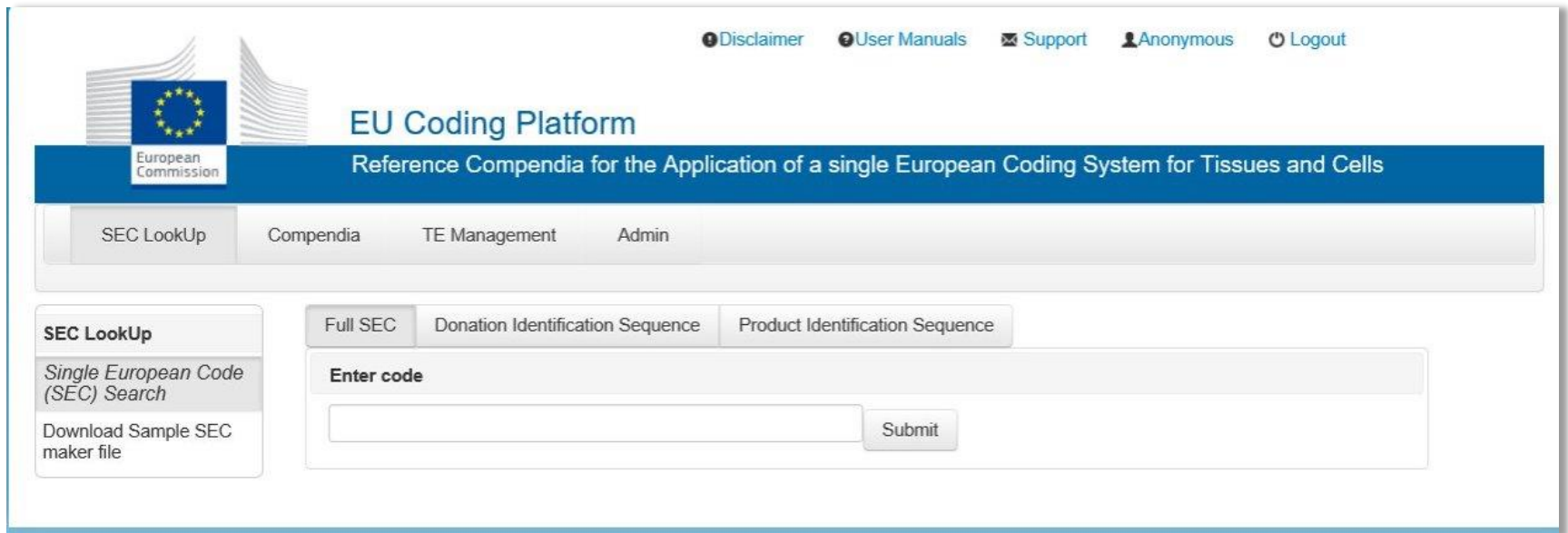
EC SANTE, 2016



EU Coding Platform:

Link to EU Coding Platform:


<https://webgate.ec.europa.eu/eucoding/>



The screenshot shows the EU Coding Platform interface. At the top right, there are links for [Disclaimer](#), [User Manuals](#), [Support](#), [Anonymous](#), and [Logout](#). The main header features the European Commission logo and the text "EU Coding Platform" and "Reference Compendia for the Application of a single European Coding System for Tissues and Cells". Below the header is a navigation menu with buttons for "SEC LookUp", "Compendia", "TE Management", and "Admin". The "SEC LookUp" section is active, showing a sidebar with "SEC LookUp", "Single European Code (SEC) Search", and "Download Sample SEC maker file". The main content area has tabs for "Full SEC", "Donation Identification Sequence", and "Product Identification Sequence". Below these tabs is a form with the label "Enter code", an input field, and a "Submit" button.



EU Coding Platform: EU Tissue Establishment Compendium



[Disclaimer](#)
[User Manuals](#)
[Support](#)
[Anonymous](#)
[Logout](#)

EU Coding Platform

Reference Compendia for the Application of a single European Coding System for Tissues and Cells

SEC LookUp
Compendia
TE Management
Admin

EU Tissue Establishment Compendium

EU TE List

Filter by Activities

EU Tissue and Cell Product Compendium

EUTC

Product List

Product Categories

[Overview Tissue Establishments](#) ▸ [TE Details](#)

Search

[Back to Full List](#)

EU TE Code	TE Name ↕	City ↕	Country ↕	
BG000866	Medical Center "Repromed" Ltd.	Pleven	Bulgaria	⊕
BG001079	Specialized Hospital For Active Treatment of Hematologic Diseases (Specialized Hospital For Active Treatment of Hemalothologic Diseases)	Sofia	Bulgaria	⊕
DE006882	Universitätsklinikum Schleswig-Holstein, Campus Lübeck, Klinik für Herz- und thorakale Gefäßchirurgie	Lübeck	Germany	⊕
DK270293	Zimmer Biomet Danmark ApS	Albertslund	Denmark	⊕



EU Coding Platform: EU TE Compendium detail/TE

Report for EU TE Code BG000866	
Name of TE	Medical Center "Repromed" Ltd.
National Code	PVNRD060111
International Code	BGPVNRD060111
Competent Authority	BG005-Executive Agency for Transplantation
Country	Bulgaria
Address	14 Vasil Aprilov Str. 5800 Pleven Bulgaria
Phone	+35964803023
E-mail	repromed@abv.bg
www	
Status	Active
Competent Authority BG005-Executive Agency for Transplantation	
Name of License Holder	Medical Center "Repromed" Ltd.
Last Update	30-May-2016
Type of Authorisation	System site inspection
Registration Detail	BG License

		Activities								
		Procurement </br>	Testing	Preservation	Processing	Storage	Distribution	Import	Export	
Type of tissues/cells	Detail									
Reproductive, Oocytes	Partner	A	A	A	A	A	A			
	Non partner	A	A	A	A	A	A			
	Fertility preservation	A	A	A	A	A	A			
Reproductive, Sperm	Partner	A	A	A	A	A	A			
	Non partner	A	A	A	A	A	A			
	Fertility preservation	A	A	A	A	A	A			
Reproductive, Embryos/Zygotes	Partner	A	A	A	A	A	A			
	Non partner	A	A	A	A	A	A			
	Fertility preservation	A	A	A	A	A	A			

A - Authorized
 S - Suspended
 R - Revoked
 C - Ceased activity



EU Coding Platform, EU TE compendium: filter by product, activity and/or member state

The screenshot displays the EU Coding Platform interface. At the top, there is a navigation bar with links for Disclaimer, User Manuals, Support, Anonymous, and Logout. The main header features the European Commission logo and the text "EU Coding Platform" and "Reference Compendia for the Application of a single European Coding System for Tissues and Cells". Below the header is a menu with options: SEC Look Up, Compendia, TE Management, and Admin.

The main content area is divided into a left sidebar and a central filter panel. The sidebar contains the following links: EU Tissue Establishment Compendium, EU TE List, Filter by Activities (highlighted), EU Tissue and Cell Product Compendium, EUTC, Product List, and Product Categories.

The central filter panel is titled "Filter:" and contains three sections:

- Pick Categories:** A list of categories with arrows for selection: Cardiovascular, Valves; Cardiovascular, Vessels; Mature Cell, Hepatocyte; Mature Cell, Keratinocyte; Mature Cell, Pancreatic Islet Cells; Mature Cell, T Cell (DLI); Members, Amelioration; Procurement
 Donation; Testing; Preservation; Processing; Storage; Distribution; Import.
- Pick Activities:** A list of activities with arrows for selection: Procurement
 Donation; Testing; Preservation; Processing; Storage; Distribution; Import.
- Tissue Establishment Name:** A text input field.
- City Name:** A text input field.
- Pick Countries:** A list of countries with arrows for selection: Austria - AT; Belgium - BE; Bulgaria - BG; Croatia - HR; Cyprus - CY; Czech Republic - CZ; Denmark - DK; Estonia - EE.

A "Submit" button is located at the bottom of the filter panel.



EU Coding Platform, EU Tissue and Cell Product Compendium: EUTC product list

The screenshot displays the EU Coding Platform interface. At the top, there are navigation links: Disclaimer, User Manuals, Support, Anonymous, and Logout. The main header features the European Commission logo and the text "EU Coding Platform Reference Compendia for the Application of a single European Coding System for Tissues and Cells". Below the header is a navigation bar with tabs: SEC LockUp, Compendia, TE Management, and Admin. The left sidebar contains a menu with options: EU Tissue Establishment Compendium, EU TE List, Filter by Activities, EU Tissue and Cell Product Compendium, EUTC (selected), Product List, and Product Categories. The main content area is titled "EUTC" and contains a table with two columns: "Product number" and "EUTC Name". The table lists 8 products, all related to cardiovascular vessels. Below the table is a pagination control showing "1-10 out of 77" and a search box. At the bottom of the table area are icons for PDF, DOC, and XLSX.

Product number	EUTC Name
98	ADIPOSE CELLS
97	ADIPOSE TISSUE
89	CARDIOVASCULAR, VALVE
2	CARDIOVASCULAR, VALVE, AORTIC
3	CARDIOVASCULAR, VALVE, MITRAL
4	CARDIOVASCULAR, VALVE, PULMONARY
5	CARDIOVASCULAR, VESSEL, AORTIC
6	CARDIOVASCULAR, VESSEL, ARTERY
7	CARDIOVASCULAR, VESSEL, OTHER
8	CARDIOVASCULAR, VESSEL, VEIN



EU Coding Platform, EU Tissue and Cell Product Compendium: ISBT 128 product list

European Commission Reference Compendia for the Application of a single European Coding System for Tissues and Cells

SEC LookUp Compendia TE Management Admin

EU Tissue Establishment Compendium
EU TE List
Filter by Activities
EU Tissue and Cell Product Compendium
EUTC
Product List
Product Categories

Product List

Search

Coding System	Product number	Product Name	Product Characteristic	Product Code	EUTC Name
A - ISBT 128	S0295	HPC, MARROW	NS/XX/r Open Plasma addet 4th container extensive	A00S0295	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
A - ISBT 128	S0304	HPC, MARROW	DMSO/XX/<-120C Open container extensive Cryc	A00S0304	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
A - ISBT 128	S0305	HPC, MARROW	DMSO/XX/<-120C Open container extensive Cryc	A00S0305	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
A - ISBT 128	S0306	HPC, MARROW	DMSO/XX/<-120C Open container extensive Cryc	A00S0306	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
A - ISBT 128	S0307	HPC, MARROW	DMSO/XX/<-120C Open container extensive Cryc	A00S0307	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
			DMSO/XX/<-120C Open		PROGENITOR CELLS



EU Coding Platform, EU Tissue and Cell Product Compendium: EUTC code

Product nr	EUTC name
78	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
79	PROGENITOR CELLS, HEMATOPOIETIC, CORD BLOOD
80	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
81	PROGENITOR CELLS, HEMATOPOIETIC, UNSPECIFIED
76	MATURE CELLS, T CELLS (DLI)



European coding system: application of SEC

Tissue Establishment (TE)	SEC-DI	SEC-PI
T&C distribution for human application	YES	YES
T&C sent to TE2 for distribution for hum. applic.	YES or YES	YES NO
T&C sent to TE2 for processing and distribution	YES	NO
T&C sent to 3d party for process. and return to TE	YES	NO
T&C distribution to ATMP manufacturer	YES	NO

SEC-DI: SEC-donation identification sequence; SEC-PI: SEC- product identification sequence



European coding system: application of SEC

Requirements for TEs

- Allocate a donation identification sequence (SEC-DI) after procurement /reception of T&C, or when importing T&C.
- Do not modify the SEC DI once it is allocated to T&C released for circulation.
- Use one of the permitted product coding systems at the latest before distribution for human application.
- Allocate a SEC at the latest before their distribution for human application.
- SEC on the label of T&C, unless label size precludes SEC application (then: unambiguous link through accompanying documentation).

One exclusion

- Reproductive cells from partner donation.



SEC implementation

Date in storage	Date of distribution		
	<29/04/17	29/04/17–29/10/21	>29/10/21
<30/10/16	NO SEC	NO SEC	SEC
30/10/16 -29/04/17	NO SEC	SEC	SEC
>29/04/17	-	SEC	SEC



Conclusion

- 1. Application of SEC: start: 29/04/2017.**
- 2. Transitional period for T&C already in storage on 29/10/2016.**



Thank you

