# Transparent MedTech User Manual

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TUE 12:30 PM

MedTech Europe from diagnosis to cure



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## 1. The Transparent MedTech platform

#### 1. Introduction

Transparent MedTech is the central database where Companies are to publish the Educational Grants they provide to Healthcare Organisations based or registered in the MedTech Europe Geographical Area<sup>12</sup> in accordance with the MedTech Europe Code of Ethical Business Practice ("the Code").

This also includes any financial allocation to medical education provided to for-profit entities such as Professional Conference Organisers.

### 2. Scope: Educational Grants

Educational Grants are defined in the Code as follows:

**Educational Grants**: means provision of funding, Member Company or third party products • or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

Educational Grants are further regulated in Chapter 4, Section 3 of the Code. In particular, the Code notes that Educational Grants can be provided for the following (non-exhaustive) purposes:

- Support for Third Party Organised Educational Events, including: а
  - 1. Support for HCP Participation at Third Party Organised Educational Events
  - 2. Support for Third Party Organised Educational Events
- b. Scholarships and Fellowships
- Grants for Public Awareness Campaigns C.

<sup>&</sup>lt;sup>1</sup> MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located (Switzerland, Turkey, Russia and the countries covered by Mecomed, the Middle East and North Africa Association). <sup>2</sup> The countries covered by Mecomed are not within the scope of the disclosure obligation for the first

reporting period (2017).



#### 3. Format of the publication

Educational Grants are disclosed in Transparent MedTech under two different categories:

- a. Support for Third Party Organised Educational Events (which includes points a.1 and a.2 above) and,
- b. Any other Educational Grant (including points b and c)

#### 4. Accessing the system

Transparent MedTech, as one of the MedTech Europe initiatives in the Ethics and Compliance area is hosted in <u>www.ethicalmedtech.eu</u>





# 2. Company Account(s)

#### 1. Account management

Companies are free to choose the internal arrangement they will use to disclose the Educational Grants. The system allows for reporting of Educational Grants at European level (with one single account), or the creation of as many accounts as necessary for subsidiaries, branches, or other dependent entities.

Each Company will nonetheless need to create **one** Master Account which will be approved by the MedTech Europe Secretariat.

Once this Master Account has been created and approved, Companies are free to create Subsidiaries (please note this is a generic name for accounts dependent on the Master Account, it is not meant to have any legal implication).

#### 2. Master Account creation procedure

Ideally, your company should create a dedicated e-mail address for transparency purposes. This will make it easier to transfer the account if there is an eventual change of roles in your organisation, and will also help further anonymise interactions related to the Transparency system (such as the contestation of disclosures system). This account can be for instance "transparency@company.com".

#### Account creation steps:

Navigate to the main page of Transparent MedTech (<u>http://transparentmedtech.eu/medtech-public/#/accueil</u>) and click on "<u>Company access</u>", on the right top corner of the screen.





Once in the Company Area, click on "Register"

	REGISTRATION
	If you don't have a login, you must register first by clicking the button « Register ».
	If your company is composed of several subsidiaries having to declare by themselves you only have to register the main company.
	Register
Login	

In the following screen, please enter the requested information to create the Master Account for your Company.

All fields are mandatory except for the Phone of the main contact person.

**Important**: It is recommended to use the generic transparency account mentioned at the beginning of this section to create this account.

INFORMATION ABOUT YOUR COMPANY	
Company name	
· TAV	
Postal code 🔸	
Country •	Sélectionnez un pays *
MAIN CONTACT (ADMINISTRATOR)	
First name	
Lastname •	
Mail •	
Phone	
	Q Cancel e Save

Once you have entered all the required information, click on "Save". You will see the following screen:

INSCRIPTION VALIDATION
Your company has been registered but is not yet activated. An email has been sent to the administrator with a link to follow for validating your company.
The Medtech transparency team.



You will receive a verification request e-mail in the address provided as the Main Contact (Administrator). Copy the link you will find in the e-mail and paste it in an internet browser

[Medtech Europe Transparency] Email verification
Transparency MedTech Europe
Sent: Wed 20/09/2017 12:49
Hello,
You asked an account for Medtech Europe transparency for the company:
For connecting the application you first have to validate your email. Please click the link provided below or vopy paste the url to your navigator.
http://transparentmedtech.eu/medtech-company/flow/validation?identifiant=pablo.rojas abad&cleActivation=20ed0889801b7a816e9ff288a89601c7d4a37b293f24b57a97a5a5cd91e41415
The Medtech Europe Transparency team

Please note that in some cases, like the one shown above, your e-mail software may not recognize the full link, and clicking in the hyperlinked part will result in the following error message being displayed.

#### VALIDATION ERROR

The activation key is incorrect or your account has already been validated

The TransparentMedtech team.

To ensure this does not happen, manually copy and paste the full link in your preferred internet browser. Once you have done this, you will see the following screen:

SUCCESSFUL VALIDATION	
Your email address has been validated but the account of your company is not yet active. Your account will be email with your password information information will be sent after your account validation.	e validated by our teams. An
The TransparentMedtech team.	
	Back to main page



You will also receive the following e-mail:



<u>Very Important</u>: This e-mail needs to be saved and kept at hand. Your login <u>username</u> is included in it, almost at the bottom of the e-mail (see above). It will be a combination in the following format: "firstname.lastname"

At this stage, please **contact the MedTech Europe Secretariat** (<u>ethics@medtecheurope.org</u>) to let us know that you have successfully validated your Master Account e-mail, and you are awaiting activation. We will only activate a Master Account once we verify the account has been created by the right person within the organisation.

Once we activate your account you will receive the following e-mail:



<u>Very Important</u>: This e-mail also needs to be saved and kept at hand. Your login <u>password</u> is included in it, almost at the bottom of the e-mail (see above).



You can now log into the system using the combination of the provided username and password in the Company Access page:

5	Med	Tech Europe from diagnosis to cure		
	CONNECTION	INFORMATION		REGISTRATION
				lf you don't have a log
	Login	name.surname		If your company is co
	Password			
		Forgotten password ?		
			Login	

Once logged in, the main Company Site page looks like this:

MedTech Eu	ICOPE is to cure	MedTech Europe
Welcome >		
Main menu	WFLCOME	
My declaration		
* Declaration importation		
A My objections		
Documentation		
CSV Format specification		
ŵ CSV tool kit		



### 3. Subsidiary Account creation procedure

To create a Subsidiary Account, you will first need to click on "My company"

X	from diagnosis to cure	
	Welcome >	
	Main menu	WELCOME
	O My declaration	
	* Declaration importation	
	A My objections	
IF		
•	Documentation	
	CSV Format specification	
	⋒ CSV tool kit	

This page contains many different useful options that we'll tackle in the following chapters. To create a Subsidiary Account, please scroll to the bottom of the page. Click on "<u>Add subsidiary</u>"

COMPANY SUBSID	DIARIES					
Company identifier	Company name	VAT	Country	Creation date	Status	Action
		No reco	rds found.			
					Add subs	idiary



You will be directed to a page identical to the one sued to register your Master Account. Once you have completed the required fields, click on "<u>Save</u>".

INFORMATION ABOUT YOUR COMPANY	
Company name 🔸	
VAT -	
Postal code 🔸	
Country •	Sélectionnez un pays 🔹
MAIN CONTACT (ADMINISTRATOR)	
First name 🔸	
Lastname 🔸	
Mail •	
Phone	
	• Cancel • Save

Once you have saved the registration, you will be able to see the registered subsidiaries at the bottom of the "My Company" page:

Company identifier	Company name	VAT	Country	Creation date	Status	Action
FHEYCICS	medtech subsidiary	123456754322	Belgium	20/09/2017	Waiting	^
ZMWXAYYE	medtech subsidiary 2	123132123	Germany	20/09/2017	Waiting	<u>^</u>

Only the administrator of the Master Account can create Subsidiary Accounts. To be able to do this the email addresses provided when creating them need to be verified just as it was done for the Master Account, so an e-mail will be sent to the registered e-mail address:

[Medtech Europe Transparency] Email verification
Transparency MedTech Europe
Sent: Wed 20/09/2017 15:19
Dear,
You asked an account for Medtech Europe transparency for the company: medtech subsidiary (FHEYCICS).
For connecting the application you first have to validate your email. Please click the link provided below or vopy paste the url to your navigator.
http://transparentmedtech.eu/medtech-company/flow/validation_compte?
identifiant = pablo.rojasabad & cleActivation = fb6eab5adde 8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5addeab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5addeab5addeab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5addeab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5addeab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab5adde8817b95fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce320859e6fc2deab596fc2deab596fc2deab596fc2deab580fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff9080ce1c71d7d73951a4e81ce3208596fc2deab596fcb1daeaff90806e1ce3208596fcb1daeaff90806e1ce3208596fc2deab596fcb1daeaff9080fcb1daeaff9080fcb1daeaff9080fc8deab596fcb1daeaff9080fcb1daeaff
one done, you will be able to access your company space with the login below : Login : pablo.roiasabad
The Medtech Europe Transparency team



Once the e-mail address has been correctly validated you will see the following message (if you receive an Error message please try copying and pasting the link in your browser again):

SUCCESSFUL VALIDATION						
Your company has been validated. An email has been sent to the administrator containing the password	information.					
The medtech transparency team						
	Back to main page					

The Subsidiary Accounts are now active and can be used through the Master Account using the blue action button(s).

COMPANY SUBSIDIARIES										
Company identifier	Company name	VAT	Country	Creation date	Status	Action				
FHEYCICS	medtech subsidiary	123456754322	Belgium	20/09/2017	Waiting					
ZMWXAYYE	medtech subsidiary 2	123132123	Germany	20/09/2017	Waiting					
Add subsidiary										

Or they can also be accessed using the specific account created for them at the time of their registration. Subsidiary Accounts have the same functionalities as Master Accounts in terms of reporting, but cannot create further levels of Subsidiary accounts.

To delete a Subsidiary Account, please contact us in <u>ethics@medtecheurope.org</u>.



#### 4. Master Account management

MAIN CONTACT (ADMINISTRA	TOR)	
First name	•	
Surname	•	
E-mail	•	Reset password
Phone		
		Save

The Master Account details can be changes in the My Company page:

Please note that even if the First name and Surname of the administrator is changed, the login details will not.

Changing e-mail is possible by introducing the new desired e-mail address in the E-mail field. After all changes are introduced, please do not forget to click on "Save".

#### 5. Creating additional accounts for reporting

You can create additional accounts for users to access the system and report.

To do this, you need to access the "My Company" page and scroll down to the "CONTACT(S) IN CHARGE OF DECLARATION" area. Click on "Add new Contact".

CONTACT(S) IN CHARGE OF DECLARATION								
First name Surname E-mail Phone Status								
		No contact in cha	rge of declaration					
• Add new contact								



Fill the fields and click in the green icon.

CONTACT(S) IN CHARGE OF DECLARATION									
First name	Surname	E-mail	Phone	Status					
						Ē			
					• Add	new cont	tact		

An e-mail will be sent to the e-mail address requesting verification of the account:

[Medtech Europe Transparency] User account creation
Transparency MedTech Europe
Sent: Fri 22/09/2017 17:15
To:
Dear,
A request to create a user account Transparency Health was conducted for the company
To log in you must first verify your email , click the link below or paste it into your browser .
http://transparentmedtech.eu/medtech-company/flow/validation_utilisateur?
identifiant=erwre.werwerwr&cleActivation=64443afd87be7517a52053a3a3abdcfd48709e9734de97324895cec09145a48d
After this confirmation, you can then access your enterprise space with login below:
Login :
The Medtech Europe Transparency team



Once the account has been verified, the user will receive another e-mail with the password:

[Medtech Europe Transparency] Account validation
Transparency MedTech Europe
Sent: Fri 22/09/2017 17:16
To:
Hello,
We inform you of account validation for society:
You will find the password for you to access your business space : password:
To recall your login sent to you in the first email .
The Medtech Europe Transparency team

#### 6. Creating additional accounts for managing objections

The process to create additional accounts for managing objections raised regarding declarations is essentially identical to the process described above for creating additional reporting accounts (Section 2.5), just click on the "Add new contact" button in the "CONTACT(S) IN CHARGE OF OBJECTION DEMAND" AREA and follow the steps indicated in the section above (2.5).

CONTACT(S) IN CHARGE OF OBJECTION DEMAND									
First name Surname E-mail Phone Status									
		No contact in charge of	demand of rectification						
	• Add new contact								



**3. Disclosing** 1. Manual Disclosure

To manually disclose Educational Grants, please click on "My declaration".

Main menu							
My declaration							
* Declaration importation							
A My objections							
≗ My company							
Documentation							
CSV Format specification							
⋒ CSV tool kit							

In the following screen you can search all declarations made by your company or companies.

MY DECLARATION									
IST OF REGISTERED DECLARATIONS									
Company	GHNYFVC	HNYFVOL - MedTech Europe							
Year	GHNYFV	OL - MedTech Eu	irope						
Status	All	:S - medtech sub	sidiary	-					
Beneficiary name	Beneficiary name								
Declaration identifier									
								P Search	
ld ≎ Year ≎ Beneficiary ≎	Amount ©	Currency ©	Declaration date	Nature 🗢	City 🗢	Postal code 🛇	VAT \$	Country 🗢	
			Search r	eturned no results					
■ Add a new declaration									



You can also enter a declaration manually from this screen. Click on "Add a new declaration"

MY DECLARATION									
LIST OF REGISTERED DECLARATIONS									
Company	GHNYFVOL - MedTe	HNYFVOL - MedTech Europe							
Year	GHNYFVOL - MedT	ech Europe							
Status	All	an outpound y	-						
Beneficiary name									
Declaration identifier									
							P Search		
ld ≎ Year ≎ Beneficiary ≎	Amount 🌣 Currency	Declaration date	Nature 🗘	City 🗢	Postal code 🔅	VAT \$	Country 🗢		
		Search	returned no results						
						E Add a	new declaration		



The manual declaration page looks like this:

DECLARATIO	N DETAILS					
BENEFICIARY INFORMATION						
VAT	123456					
	Beneficiary doesn't have VAT					
Unique identifier	Select unique identifier	•				
Company name	Test Company					
Address	123 Test Street					
Postal Code	1234					
City	Testville					
Country	Belgium	•				
DECLARATION INFORMATION						
Date	02/04/2015					
Amount	12345					
Currency	Euro	•				
Nature	Support to Educational Events (inc. attendance)	•				
	This is just a test.					
Object		_				
Publication state	Not Published					
			় ⇔ Cancel 🛛 🖻 Save			

Once you have finished filling the information, click on save.

**Important**: In case the beneficiary doesn't have a VAT or because of local laws and regulations it cannot be published without the entity's consent, please let us know in <u>transparency@medtecheurope.org</u>. If you



are the first company to encounter this problem in that particular country, you will have the opportunity to propose a different unique identifier. The new category of unique identifier will be added to the drop-down menu that you can access once you click in the "Beneficiary doesn't have VAT" tick box as shown below.

Unique identifier     Select unique identifier       Company name     Select unique identifier		Beneficiary doesn't have VAT	
Company name Select unique identifier test	Unique identifier	Select unique identifier	
	Company name	Select unique identifier test	

The declaration will now be shown in the "My declarations" page once you search in the correct year.

MY DECLARATION											
LIST OF REGISTERED DECLARATIONS											
Company GHNYFVOL - MedTech Europe							•				
Year 2015							•				
	Status All										
Beneficiary name											
Declaration identifier											
	P Search									Search	
ld ≎	Year ≎	Beneficiary ¢	Amount ¢	Currency ≎	Declaration date	Nature 🗘		City 🗢	Postal code	VAT \$	Country 🗢
3559	2015	Test Company	12345.0	EUR	02/04/2015	Support to Educational Events (inc. attendance)		Testville	1234	123456	Belgium

To edit any declaration, just click on it in the list, introduce the changes and save it. You can also desactivate the declarations simply by clicking on "desactivate".



#### 2. Bulk disclosure

To disclose the information for several HCOs at once, a specific excel template must be used. This template can be downloaded from the main menu.

Main menu							
My declaration							
* Declaration importation							
A My objections							
≗ My company							
Documentation							
CSV Format specification							
⋒ CSV tool kit							

The CSV tool kit includes a small guide on how to use the excel template in diferent versions of Excel.

Proceed filling the Excel template with the required information. **Please note the only optional field is the** "**Object**" field.

**Important:** Please make sure you introduce the correct Company ID in the first field of the template. Your Company ID can be found here:

Main menu	ACCOUNT DETAIL
My declaration	
* Declaration importation	
A My objections	Company name   Testing
≗ My company	VAT Number • 234231231
Documentation	
CSV Format specification	Company identifier VIKXXGEJ
⋒ CSV tool kit	Postal code • 1234
	Country · Belgium

Your subsidiaries will have a different Company ID.



The fields "Currency", "Country" and "Educational Grant Type" require specific formats for the information in them.

You can find the correct format for these fields in the "Value list" tab.



Once all the information has been filled, click on the "Export to CSV" button on the right of the Excel template and save the resulting csv file.

CURRENCY_CODE	OBJECT			
		Export to	o csv	
EUR	Test object (please insert your own)			

This file has to be uploaded in the "Declaration importation" page, by clicking in the "Select file to upload" button (or equivalent in your browser's language) and then on "Import".

Main menu	DECLARATION IMPORTATION
Declaration importation	IMPORT CSV FILE
My objections  My company	Import

Any mistakes in the form will be highlighted in the "Error in the CSV" area. Please fix them, export the file again and re-upload the resulting CSV file.

ERROR FOUND IN CSV									
(d <d>&gt; (b) 10 T</d>									
#Lines Company identifier Date (dd/MM/y yyy) Recipient name city Country code Postal code Address VAT / Identifier Grant type Amount Currency code									
lines successfully controlled									
14 <4 b> b1 <b>10 v</b>									