PORTALE UNICO VALORI

BOLLINI FARMACEUTICI

Manual for Pharmaceutical Companies

1 REVISION HISTORY

Version	Date	Changes	Notes	Author
1.0	01/11/2016	First Issue		IPZS
1.1	18/11/2016	Copying an Order (para. 7.10), Packaging Data (para. 7.2 and 7.2.1), Commercial Data (chap. 9).		IPZS
1.2	28/11/2016	New procedure to surf catalogue (chap. 6)		IPZS
1.3	07/12/2016	New functions to manage catalogue		IPZS
1.4	22/12/2016	New functions to manage catalogue (upload graphics) and to manage update of personal data		IPZS
1.5	16/01/2017	New functions to manage Goods Receiver. (Insert, Update and Delete)		IPZS
2.0	28/02/2017	New features for managing graphics: Insert, Edit, Delete, Activate, import and export xml, pdf and red files. SuperUser profile release, dynamic profiling of users and management roles.		IPZS
2.1	31/05/2017	Integrated non-compliance management		IPZS
2.2	04/09/2017	Insertion of delivery data for foreign shipments E-mail notification of tracking		IPZS
2.3	09/10/2017	Download in Excel format in the Order Search section. New Role for handling nonconformity reporting. New Role for entry of goods withdrawals for foreign orders.		IPZS

2 INTRODUCTION

The Revenue Stamp – Pharmaceutical Label Portal is a project to rationalize and computerize procedures to accredit pharmaceutical companies, and to manage ordering and delivery of pharmaceutical labels, both from Customer's point of view (the pharmaceutical company) and in terms of administration/production (IPZS).

It was created under auspices of the Italian State Mint – *Istituto Poligrafico e Zecca dello Stato S.p.A.* (IPZS), with the aim of providing those involved in the process with a tool that, as well as assisting in managing orders, production and shipping, also allows single labels to be traced pursuant to the Commission Delegated Regulation (EU) No. 2016/161 of 2 October 2015.

The present document aims to provide a detailed description of the functions that the **Revenue Stamp – Pharmaceutical Label Portal** offers companies to manage orders; in particular, this version refers to the set of functions featured on the 1.x version of the Portal, conceived specifically for pharmaceutical companies, i.e.:

- Authentication and first access portal (with SuperUser profile activation)
- Setting and changing user data
- procedure for changing password and password recovery procedure
- User Dashboard
- Catalog AIC and Product Search
- Processing and Search Orders
- Business Data
- graphics management
- Management of users

3 SUPERUSER PROFILE

All users credited to 2/28/2017 (version 1.5 of the software), were associated with the Profile Partner. It allows you to use the following core capabilities:

- catalog navigation
- inclusion of new AIC codes in product catalog in direct ownership
- Insertion of proxies (AZ. delegate, manufactures or dealers) in product catalog in direct ownership
- Loading new graphics and/or update by uploading xml file (produced by BolliniViewer)
- Search and insert Orders (drafts/templates)
- Approving orders
- Display goods recipient, invoice recipients, paying performers
- Insert/modify goods recipient's address book
- change personal data

With the release of version 2.0 of the portal scheduled for 1/3/2017, on the portal is also activated the SuperUser profile which provides, in addition to the above functions, the following:

- creating new users and profiling management
- view, modify, or disable existing users
- managing graphics (both reading and writing) associated with the company’s products

The table below shows the map of features on those two profiles:

Scope	Functionality	Partner	SuperUser
Catalog	Insert new AIC	x	x
	Enter delegation	x	x
	AIC Search	x	x
	Browse catalog	x	x
Graphics	Graphics detail		x
	Insert graphics		x
	Edit Graphics		x
	Active graphics draft		x
	Delete graphics		x
	Upload xml	x	x
	Export xml		x
	Export pdf		x
	Export red file (png)		x
Orders	Create order (draft/model)	x	x

	Change order (draft/model)	x	x
	Delete order (draft/model)	x	x
	Approve order	x	x
	Cancel order	x	x
	Print order (pdf)	x	x
	Search order	x	x
Commercial Data	Search and view business data	x	x
	Insert/modify goods receivers	x	x
Users	Search business user		x
	Edit users		x
	Enable/disable users		x
	Add new users		x
	User profiling		x
	SuperUser Promotion		x
	Edit personal information	x	x
	Change password	x	x
Non-Compliances	Management of Non-Compliance reports		

Starting from 3/1/2017 to all Partner Users will be automatically prompted by the system, to accept or not the SuperUser profile features, with the constraint that each company must have at least one SuperUser among enabled Users (see section 5.7). Since that date the names specified in the enabling application, downloadable from the website, will be enabled with SuperUser profile, as reported in the application itself , of wich we provide an extract:

> Pursuant to Article 7 paragraph 3 of the Ministry of Health's Decree of 30 May 2014, requests authorization for the above company to access the Portal in question.
> To this end, pursuant to and in accordance with Arts. 46 and 47 of Presidential Decree 445/2000, fully aware of the responsibility and civil and penal consequences as per Art. 76 of said Decree in the case of false and untruthful declarations, declares that he/she will make purchases, via the Portal in question, exclusively of pharmaceutical labels that the company is authorized to place on the market in Italy, or is a subject that has been authorized to do so by the licence holder.
> He/she also declares that the following persons are authorized to purchase pharmaceutical labels (the users will be registered as SuperUser, for details please see Chapter 3 of User Manual):

4 WELCOME PAGE

The Portal is available both at the address http://www.portaleunicovalori.ipzs.it/bollini and at the old address http://www.bollini.ipzs.it (managed from now on as an alias) where Users will find the welcome page. This contains:

- fields to enter login credentials consisting of username plus password
- a link to recover forgotten passwords
- a link to the Portal's Privacy section

- a link to the Contacts section
- a link to the Conditions of Use section

4.1 Authentication

Portal Authentication requires Users to enter their Customer Code and a Password supplied by IPZS. The Customer Code consists of an eight-digit numeric code, while the password is a string with a minimum length of 8 characters and at least one capital letter.

4.2 Password Forgotten

This procedure has been specially designed to recover a User's password when it has been forgotten. By clicking on the link, the system will ask Users to enter their username, and a CAPTCHA code:

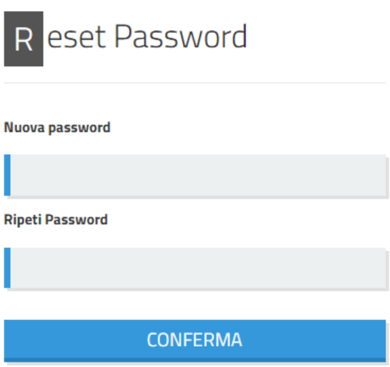
Users should enter the letters in the image in the second field and then click on Send Request. If the image is difficult to read it is possible to ask the system to generate a new image by clicking Reload .

By clicking Send Request the system will send an e-mail associated with the username entered, containing instructions to reset the personal password. The e-mail received will read as follows:

> Dear Name Surname,
>
> On the **Revenue Stamp – Pharmaceutical Label Portal** an operation has been requested to reset the password for your account. To carry out the procedure, please click here within **24 hours** of receiving this e-mail.
>
> Once this time limit has been exceeded, it will be necessary to repeat the procedure to recover the password.
>
> If the link does not work, please copy the following address http://www.portaleunicovalori.ipzs.it/bollini/reset_pwd?pin=ZqebUUKTEghxq8pKzKDg4zzo5DrqZrZH, paste it into a new window on your browser, and then follow the instructions to complete the operation.
>
> With best regards,
> Istituto Poligrafico e Zecca dello Stato S.p.A.

This e-mail is therefore a disposable "token" valid for 24 hours, which will allow the User – if used within the time limit – to set a new personal password using the link. Once this time limit has been exceeded, if unused, the "token" will be automatically cancelled.

Clicking on the link in the e-mail brings up a page with the fields New Password and Repeat Password:



By filling in the above fields, and clicking Confirm, the system will substitute the old password with the new one, and the procedure can be considered concluded.

4.3 Privacy

This section shows the policies used by the **Revenue Stamp – Pharmaceutical Label Portal** relating to Privacy – the Processing of Personal Data and the Cookies used by the system. Users can consult the web page, and/or download the contents in PDF format.

4.4 Contacts

This is a section dedicated to contacts, where Users can find all the channels to contact IPZS for assistance.

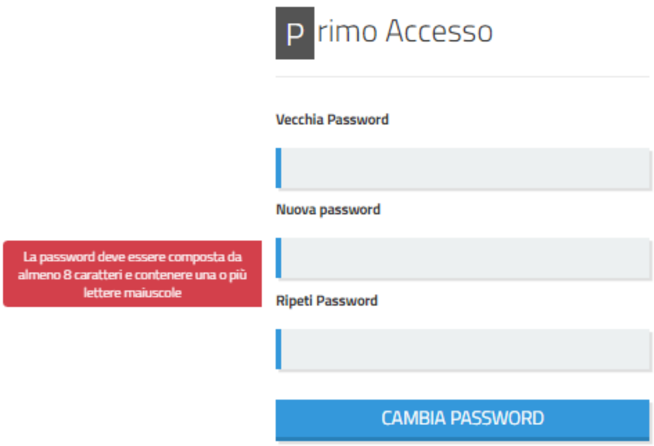
4.5 Conditions of Use

This section contains the General Supply Conditions both as a web page and in a downloadable PDF format.

5 FIRST LOGIN TO THE PORTAL

5.1 Changing password at first login

At first login, the Portal will immediately ask to change the initial password provided by IPZS to a personal one, consisting of at least 8 characters with one or more capital letters:



This new password must be repeated – as a security check – in the field Repeat Password. By clicking on Change Password the system will memorize the new personal password.

5.2 Inspection of the portal policies

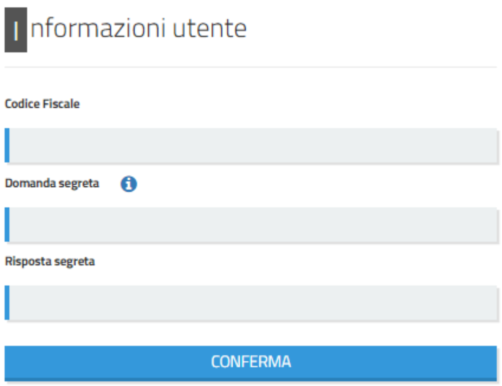
The next step is to inspect the Privacy and Cookie policies used by the Portal; this step is mandatory to use the Portal's functions. After reading the information, click <u>Inspected</u> and then <u>Continue</u>.

5.3 Conditions of Use

This step shows the User the General Supply Conditions; also in this case inspection is necessary to complete the configuration of the User profile to access the Portal's functions for the first time. After reading the information, click <u>Inspected</u> and then <u>Continue</u>.

5.4 Information for Users

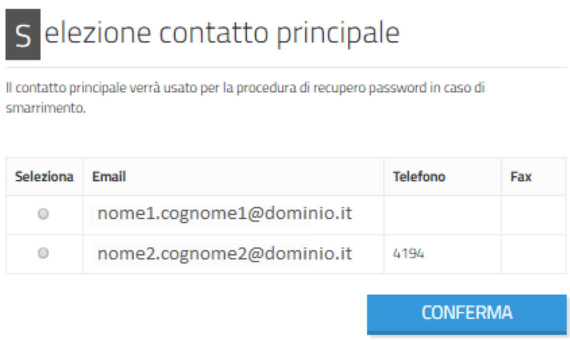
In this step, the system asks Users to enter their Tax ID, followed by a secret personal question and the answer to it. The Tax ID is needed to identify an individual connected to different companies, while the secret question and answer are used to recover the Customer Code if forgotten. Note that this information is confidential.



By completing the above fields and clicking Confirm we move to the last step.

5.5 Choosing a main contact person

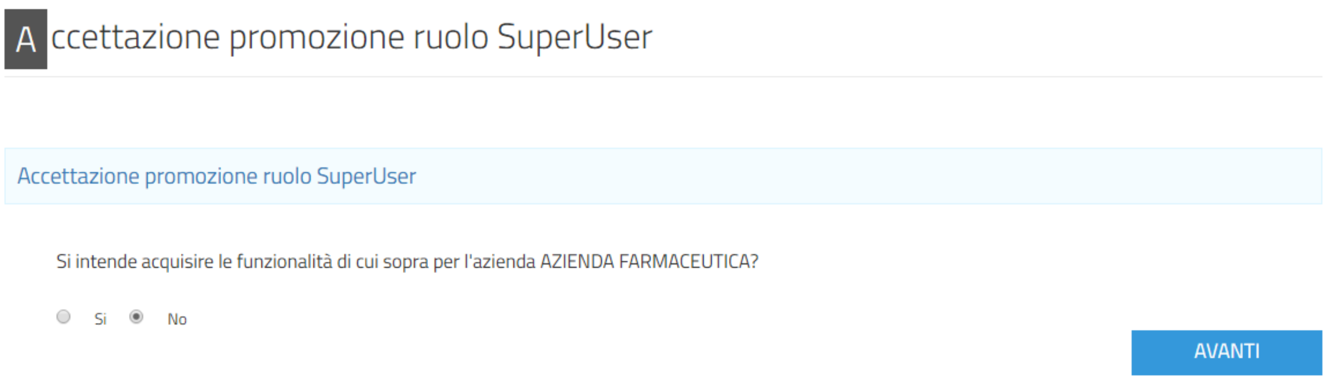
In this phase, the system asks Users to choose a main contact person, if this person works for several companies (i.e. possesses several interlocutor codes) and thus has several e-mail addresses. The main contact person will be used by the Portal to recover passwords, e.g.: the e-mail address of the main contact person is the one used to recover these:



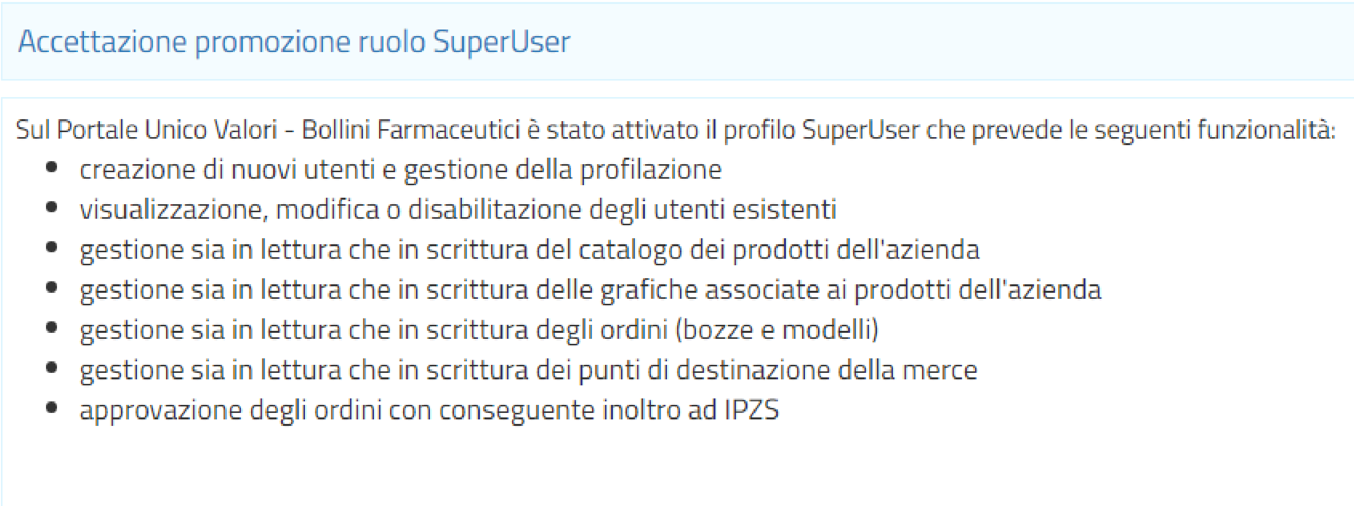
By choosing a contact person and clicking Confirm we finally return to the Portal's Home Page.

5.6 Accept SuperUser's profile

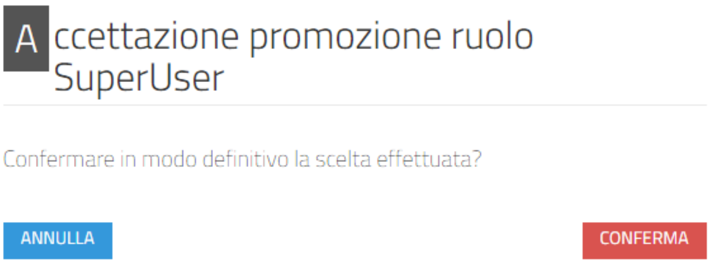
In this phase the User is prompted to accept or reject the promotion to SuperUser profile.



By clicking on "Accept SuperUser role promotion " you can view the list of features for which you’re enabled:



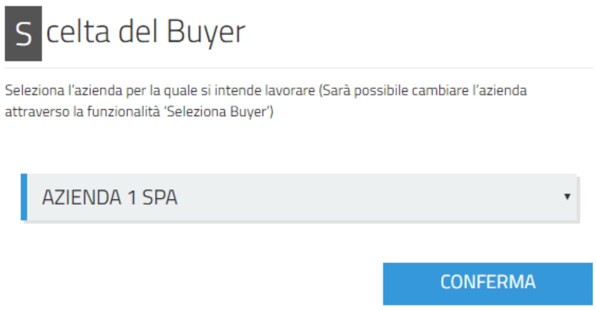
By selecting YES and clicking on the next button the portal will present a confirmation request:



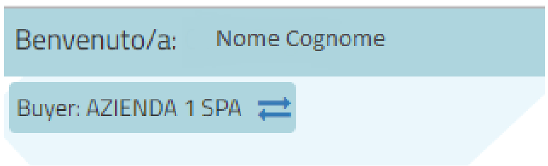
By clicking CONFIRM button the user will inherit all the roles envisaged for this profile and will access the portal’s home page. Clicking on CANCEL button will return to the previous screen (accept SuperUser role promotion). Note: selecting NO the user may refuse the assignment of profile SuperUser; in any case, each company must have at least one SuperUser for the complete management of the process.

5.7 Choice of buyer

The choice of buyer is always prompt to user after login, just in case the user is linked to more than one company, it loads the user's profile and also the data (eg. products catalogue, list of orders, etc.) related to company choice. Here the ways in which the user selects the buyer:



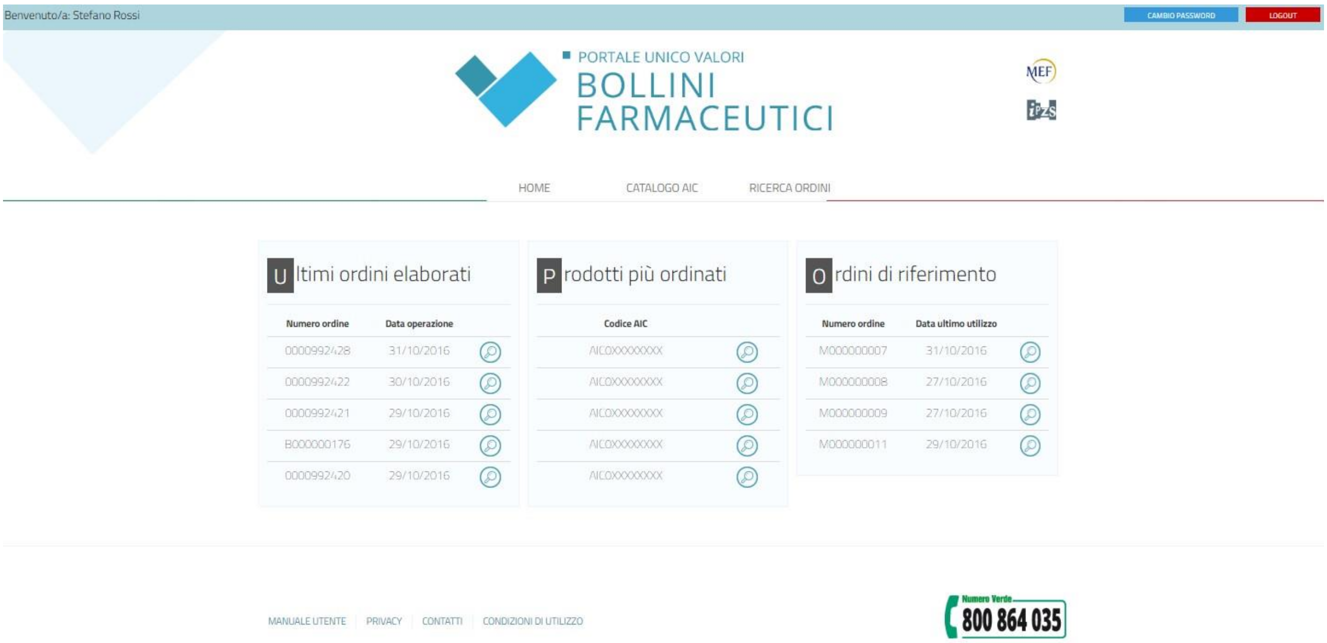
Once selected the company and clicked on confirm the system will display the home page; upper left (below the welcome message), you will see the buyer chosen in an appropriate box:



Once double clicking on the blue arrow  the system proposes the list of selectable company so you can change the reference buyers during the same browser session.

6 HOME PAGE

The Home Page will be organized as follows:



The upper bar features the welcome message and allows access to the Change Password section, or to Log out of the Portal. Instead the page footer features links to:

- User Manual
- Privacy Section
- Contacts Section
- Condition of Use Section

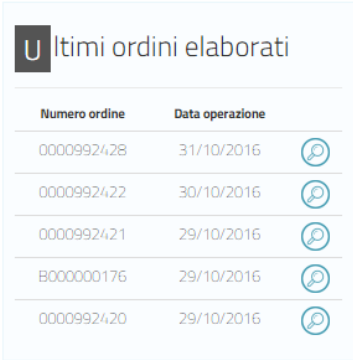
N.B.: when authenticated, the Conditions of Use section shows in the table of attachments some other documents that are not accessible to the public.

Instead, the central section of the page shows three dashboards containing:

- The last 5 orders processed by the User, if present in the system.
- The 5 most ordered products, if there are orders in the system.
- The 5 templates (or reference orders) most used by the User, if present.

6.1 Latest Orders Processed

This is a notification centre that can display from 0 to a maximum of 5 orders processed (here, “processed” means created and/or changed); in the event of 0 orders the message will be *There are no orders in the system*:



Clicking on the lens shows details of the order (see the relevant section).

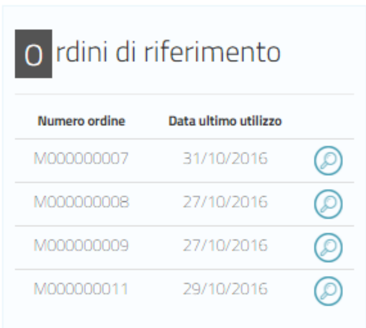
6.2 The 5 Most Ordered Products

This is a notification centre that can display from 0 to a maximum of 5 products most ordered by the User; in the event of 0 orders the message will be *No products ordered:*

Clicking on the lens shows details of the order (see the relevant section).

6.3 The 5 Most Used Reference Orders

This is a notification centre that can display from 0 to a maximum of 5 reference orders; in the event of 0 orders the message will be *There are no reference orders in the system*:



Clicking on Open shows details of the reference order (see the relevant section).

6.4 Changing a Password

Clicking Change Password opens the section to change the password where the system will ask the User for the current password, and then to enter and repeat a new one.

N.B.: *in any case, personal passwords are only valid for 50 calendar days, after which they expire; the system will therefore ask the User to enter a new personal password every 50 days. The password chosen must be different from the last three used.*

6.5 Changing personal data

This section allows you to access into 'Update your personal contacts' with a dual purpose:

- select main contact (set during the first access to the portal as specified in section 4.5)
- editing fields email, telephone and fax of the selected contact

Please remember that a user can be also associated with more than a company, possessing for each one different contacts (email, phone and fax); the selection of the main contact, allows to determine wich email address the stamps portal should use in case of loosing password (for details see section 3.2).

Therefore clicking the Personal Data button, on the top bar of the portal, displays the contacts associated with the user:

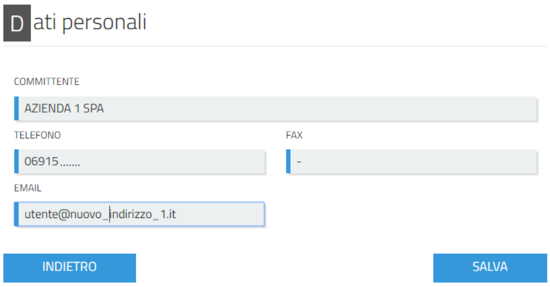
Selezione contatto principale

Il contatto principale verrà usato per la procedura di recupero password in caso di smarrimento.

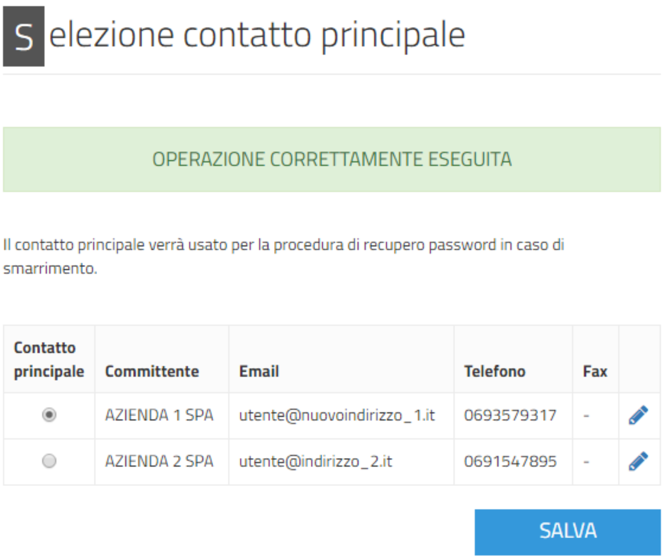
Contatto principale	Committente	Email	Telefono	Fax	
◉	AZIENDA 1 SPA	utente@indirizzo_1.it	-	-	
○	AZIENDA 2 SPA	utente@indirizzo_2.it	06935....	-	

SALVA

Changing the selection of the primary contact and clicking on SAVE, will set the new Reference contact. By clicking on the icon you can edit the fields email, phone and fax contact:



Entering new data and after click on SAVE the system will acquire the change and display when it is done the transaction message:



NOTE: the email field must always be enhanced. You can not save a contact without email or with an email not properly valorized.

6.6 User Menu

User functions can vary depending on profile; in any case the features available in the current release are as follows:

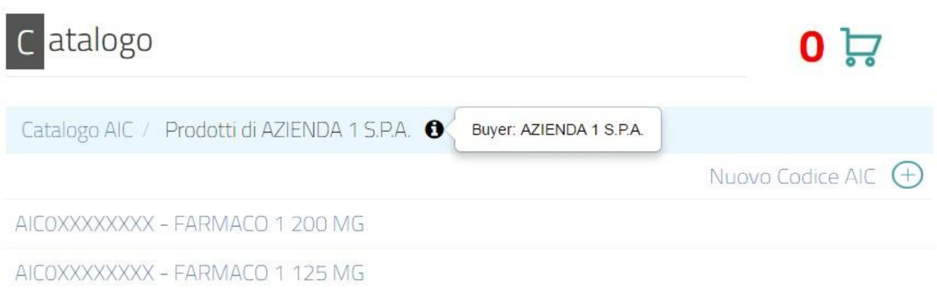
- Home: to access the Portal's Home Page
- *AIC Catalogue:* to access the product catalogue of the accredited company
- *Order Search:* to search for orders in the archive of the Revenue Stamp – Pharmaceutical Label Portal
- *Commercial Data:* to access the commercial data used by the company in orders for Pharmaceutical Labels (customer data, invoice addressees, payers and goods consignees).

7 AIC CATALOGUE

Clicking on the first level menu item AIC Catalogue closes Home and opens the company's personal product catalogue. The AIC Catalogue shows all the products that can be ordered by Users. The products are grouped by Holder Company and are categorized in *Directly Held Products*: i.e. products the company owns directly, and "indirectly held products": i.e. products that the company represents, produces, or deals in, etc.

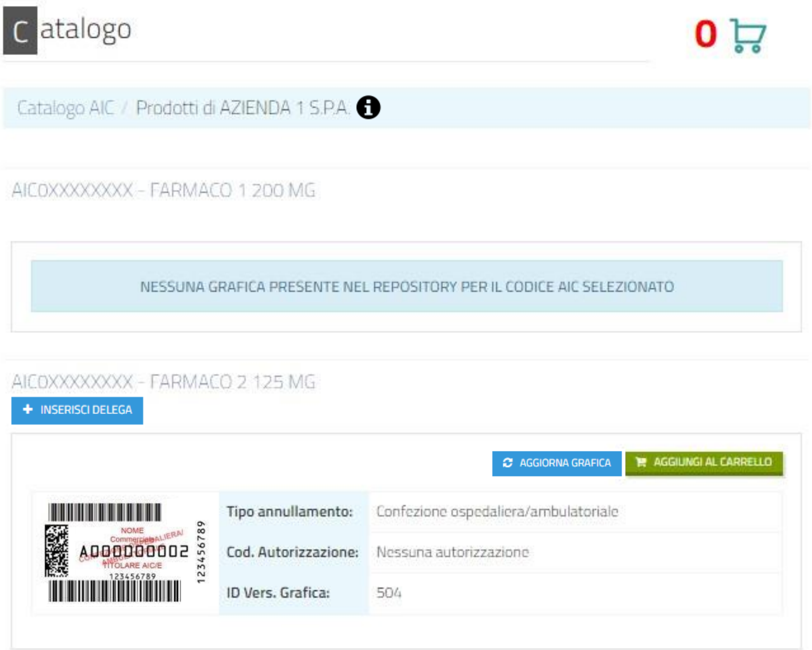
By clicking on a line, greater detail is shown, with the possibility of showing the range of AIC codes that can be ordered. At the top of the page there will be a Breadcrumb whose root is the "AIC Catalogue" link which, if clicked, opens the main catalogue, or as a sheet with the name of the holder company of the catalogue opened.

Beside the name of the holder company is an icon ℹ: by holding the cursor of the mouse above it, the system will display the name of the buyer, i.e. the name of the purchasing company where one or more products from the catalogue have been added to the basket (N.B.: in the case of indirectly held products the buyer will be different from the holder company). Every line then displays the AIC Code followed by the name of the medicine:



You can also order the test label (AIC code: AIC000000000).
By clicking on the product of interest, the system will display the details, where it will be possible to enter the graphics repository and see: a preview of the label, the type of validation, the authorization code and the ID of the "active" graphic.

For directly held products only there is a New AIC Code button, to add a new AIC to the catalogue (see paragraph 6.2).



In the example above, we show a case (Medicine 1) where there is no graphics in the system's repository, and as a result it is impossible to order that product. Instead, in the second case, the graphics 504 is show along with its features. Clicking on the image of the label will bring up a high-resolution preview (that also shows the graphics ID and the name of the medicine), which can be downloaded to the User's workstation. Instead, the button Add to Basket allows the product to be purchased (see relevant section); in any case, when one or more products are added to the basket in the product catalogue section a basket will appear (top right) containing the number of products added; in addition, pressing the AIC Catalogue main menu button will show the number of products in the basket at the top right-hand side:

Again, for directly held products, there are two buttons, Add Proxy and Update Graphics, which allow the addition of a new proxy for a given product, and to update the graphics in the IPZS graphics repository (see paragraphs 6.3 and 6.4).

7.1 Product Search

In the section to the left we find fields to search for products, in the catalogue available to Users. A search is made by entering the AIC Code of the product, or the product name, or both.

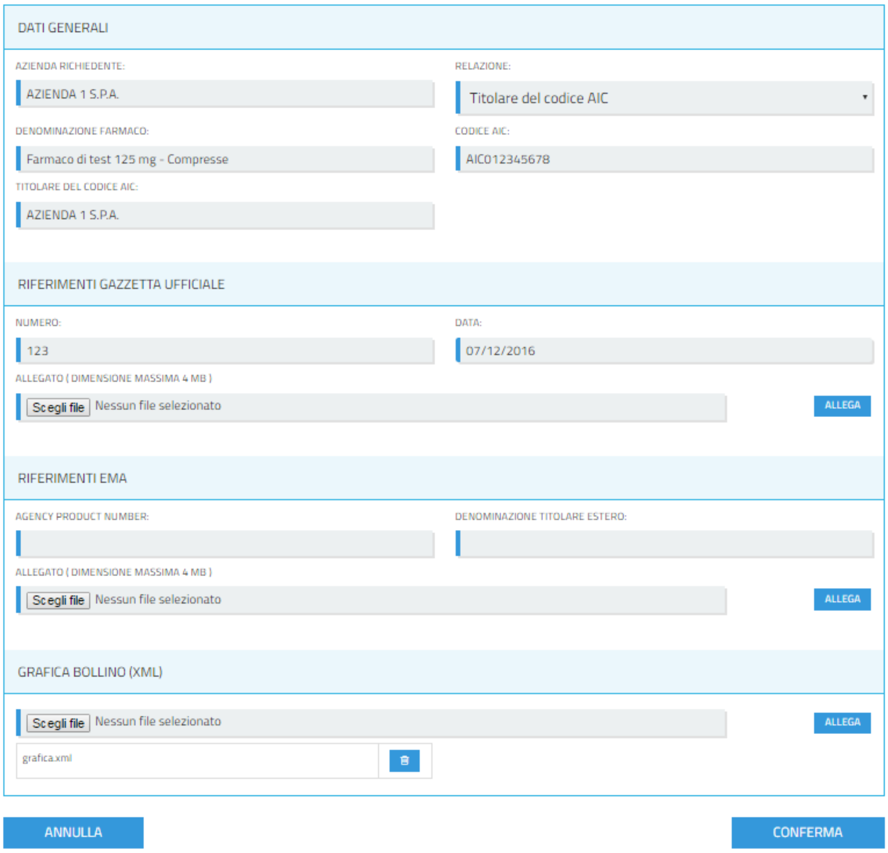
The result of the search will be displayed in the area dedicated to the product catalogue only for products that match the search criteria entered, otherwise, the message *No Result Found* will appear:

All the lines displayed are clickable to see details of the product.

7.2 Adding a New AIC

For directly held products only (blue band), this function is to request an updating of the catalogue by issuing a new AIC. In this section the following information is required:

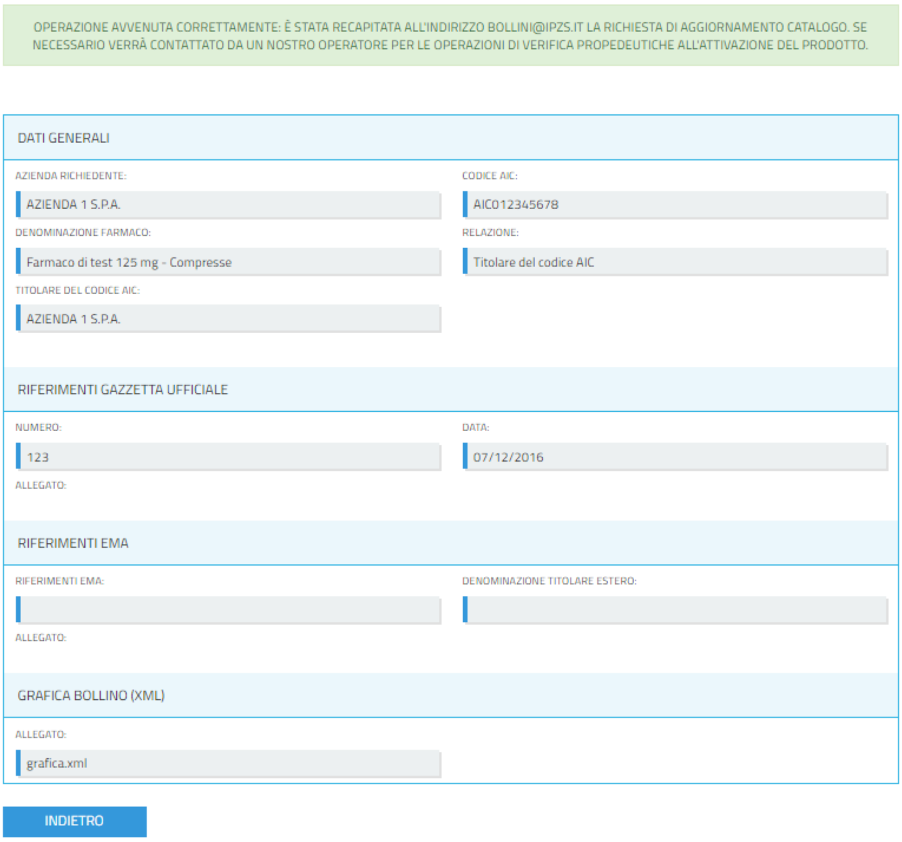
- Type of authorization (holder or representative in Italy)
- Name of the medicine
- AIC Code
- Holder of the AIC Code (appears automatically if holder is authorized)
- Official Journal (GU) References
- EMA References



All the fields are mandatory, with the restriction of specifying at least one GU or EMA reference.

If it is necessary to associate attachments (e.g. a GU scan), this should be in PDF format. Attachments cannot exceed 4MB in size.

By clicking on CONFIRM the system pre-validates the data entered, and in the case of a positive result, opens a page summarizing the data entered and sends the request by e-mail to the label office (bollini@ipzs.it). In turn, the User will receive the same e-mail as confirmation that the operation has been carried out.



7.3 Adding a Proxy

Like the addition of a new AIC, “proxy” allows the direct holder of a product to nominate a company as its “delegate", specifying the type of authorization: proxy, producer or dealer. In this section the following information is required:

- Name of the company to be delegated
- Tax ID of the company to be delegated
- Type of authorization (proxy, producer or dealer)
- Start and end dates of the proxy
- Holder of the AIC Code (appears automatically if holder is authorized)
- Official Journal (GU) References
- EMA References
- AIFA Decision (pdf)
- Proxy/Acceptance (pdf)

All the fields are mandatory, with the following exceptions:

- Start and end date of the proxy is only required if the type of authorization is for a proxy
- The Proxy/Acceptance pdf is only required if the type of authorization is for a proxy
- The AIFA Decision is mandatory only if the type of authorization is for a dealer
- At least one reference must be specified, either GU or EMA, if the type of authorization is for a producer

If attachments are included (e.g. a GU scan), the expected format is PDF. Attachments must not exceed 4MB.

By clicking on CONFIRM the system prevalidates the data entered, and in the case of a positive result, opens a page summarizing the data entered and sends the request by e-mail to the label office (bollini@ipzs.it). In turn, the User will receive the same e-mail as confirmation that the operation has been carried out.

8 GRAPHICS MANAGEMENT

By using the following features the user can manage inserting, modifying and erasing graphics associated with AIC codes. In order to direct the user towards autonomous management of the catalog, the following case studies have been identified:

<u>CASE 1: no graphics present for the specific AIC</u>
In this case the operations to be carried out are:

A. Inserting new graphics. (section 8.1)
   The system creates a graphics in a draft State. As long as the graphics is in draft status is not available for purchase and can be modified by the user.
B. Enable new graphics. (section 8.2)

   Only after you enable the new graphics, it can be purchased.

<u>CASE 2: Active graphics already exists for the specific AIC, but to be updated</u>
In this case the operations to be carried out are:

A. Changing active graphics (section 8.3)

The process of editing an active graphics provides the creation of a new graphics with a different ID version in draft State, the activation of the latter with the simultaneous elimination of the previous graphics. *Attention: in case there are one or more orders placed for IPZS containing the deleted graphics, these will be processed and produced normally, because deletion is after the confirmation of the order.*

<u>CASE 3: Active graphics already exists for the specific AIC, but it has to be deleted</u>
In this case the operations to be carried out are:

A. Deleting Active graphics (section 8.4)

Deleting an active graphics, the latter will no longer be visible in the catalog. *Attention: If there are one or more orders forwarded to IPZS containing the deleted graphics, these will be processed and produced normally, because deletion is after the confirmation of the order.*

<u>CASE 4: Graphics in Draft status for the specific AIC, but has to be deleted</u>
In this case the operations to be carried out are:

A. Cancellation Graphics in Draft (section 8.5)

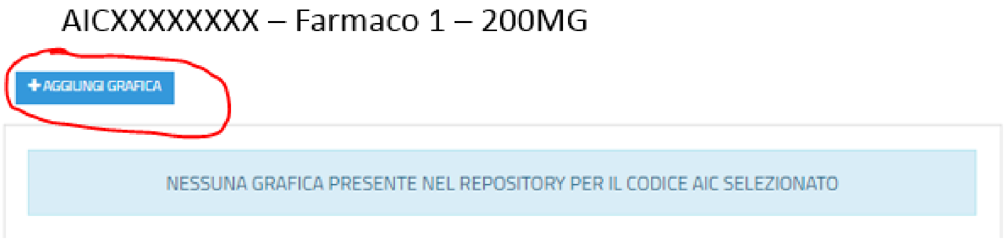
Deleting a graphics in draft State, the latter will be no longer visible in the catalog.

Additional export graphics' capabilities have been introduced. These capabilities are described in section 8.6.

8.1 Insert new Graphics

Only for products with direct ownership is available the "Add Graphics" functionality, in cases where the AIC is present in the product catalog but with no graphics or if you plan to define new graphics with different configurations*. Attention: a graphics is uniquely identified by the following triple information: < AIC, code authorization, cancellation type >;* it will be not possible to insert multiple graphics with the same triple information, but it will be possible to proceed to an update*.*

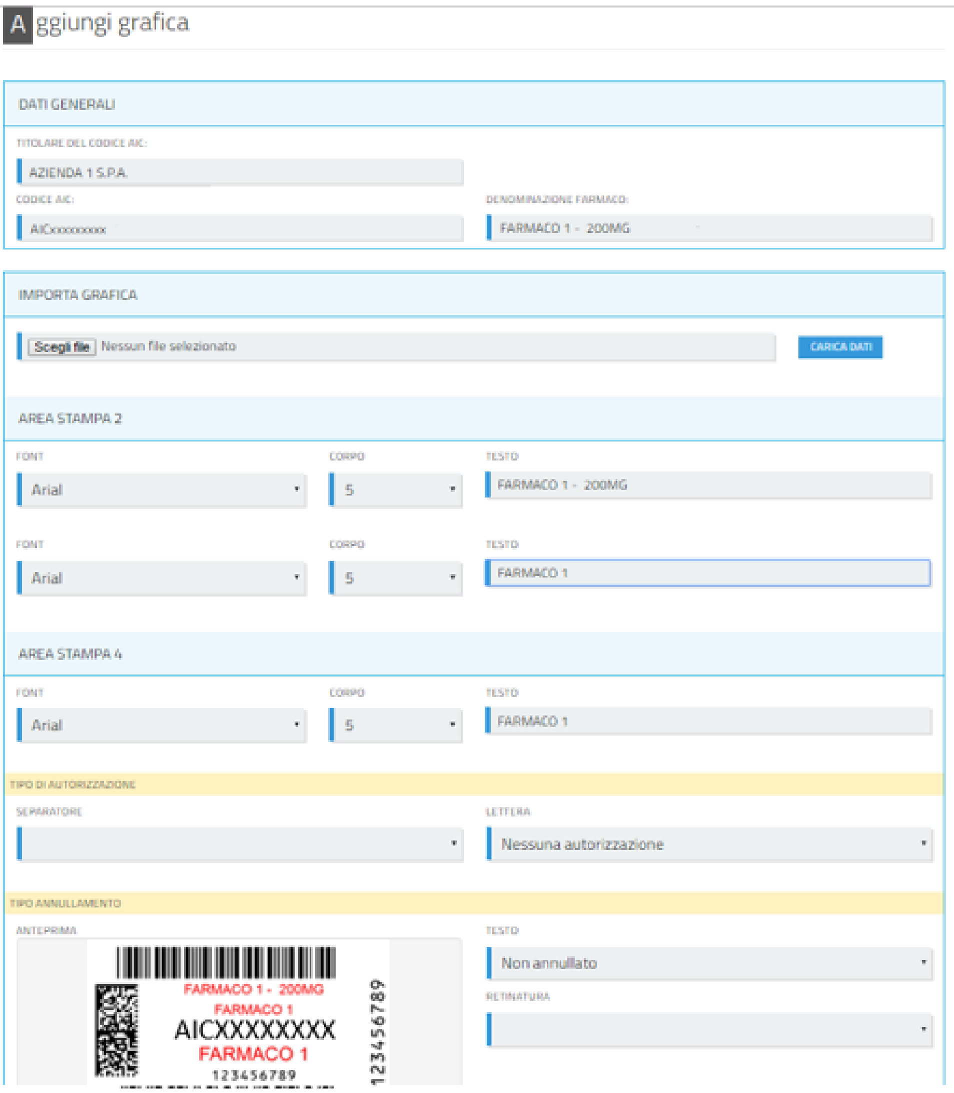
Select the AIC interested from the catalog and press "Add Graphics"



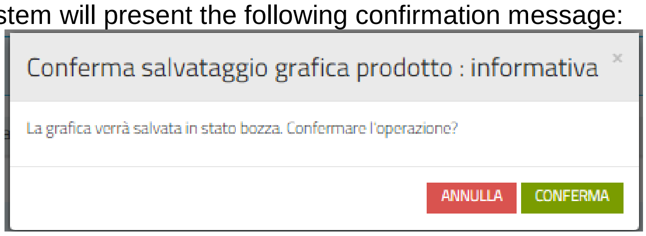
By clicking on the button *Add graphics*, the system shows a form that will report the following immutable data: *AIC code holder name, AIC code and name of the medication.*
On input, you will need to enter data about:

- Printing Area 2 row 1 and printing Area 2 row 2 (font, font size and text)
- Printing Area 4 row 1 (font, font size and text)
- type of cancellation
    - In the "Type of cancellation" section you can select text and the the cross-hatching. If in the "Text" field we choose the option "Not Canceled" and we also indicate the cross-hatching, the system will prevent us from saving the graphics. the cross-hatching is instead mandatory if in the "Text" field we indicate a value different from "Not Canceled".
- type of authorization.

Filling out the form displays the label Preview in real time so you always have a preview of the work that is being produced.
For your convenience there is the ability to import a previously defined graphics with BolliniViewer: the input field next to the button "load data" can be used to preload data into form by using the exported xml file from BolliniViewer.



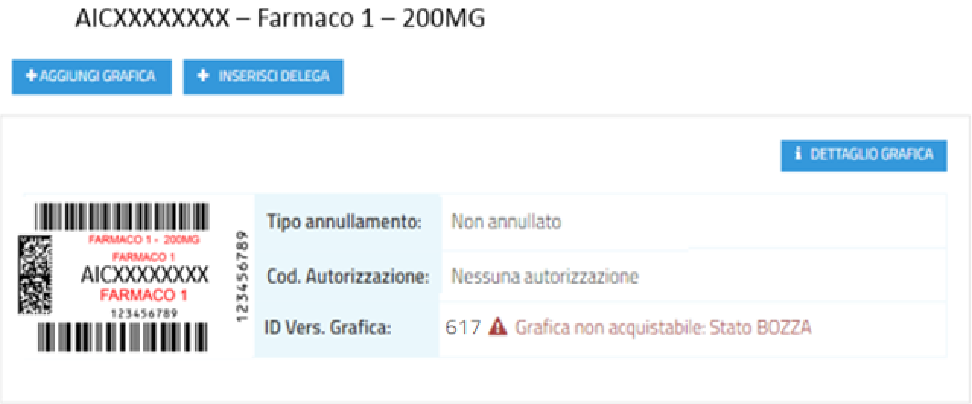
By clicking on Confirm, the system will present the following confirmation message:



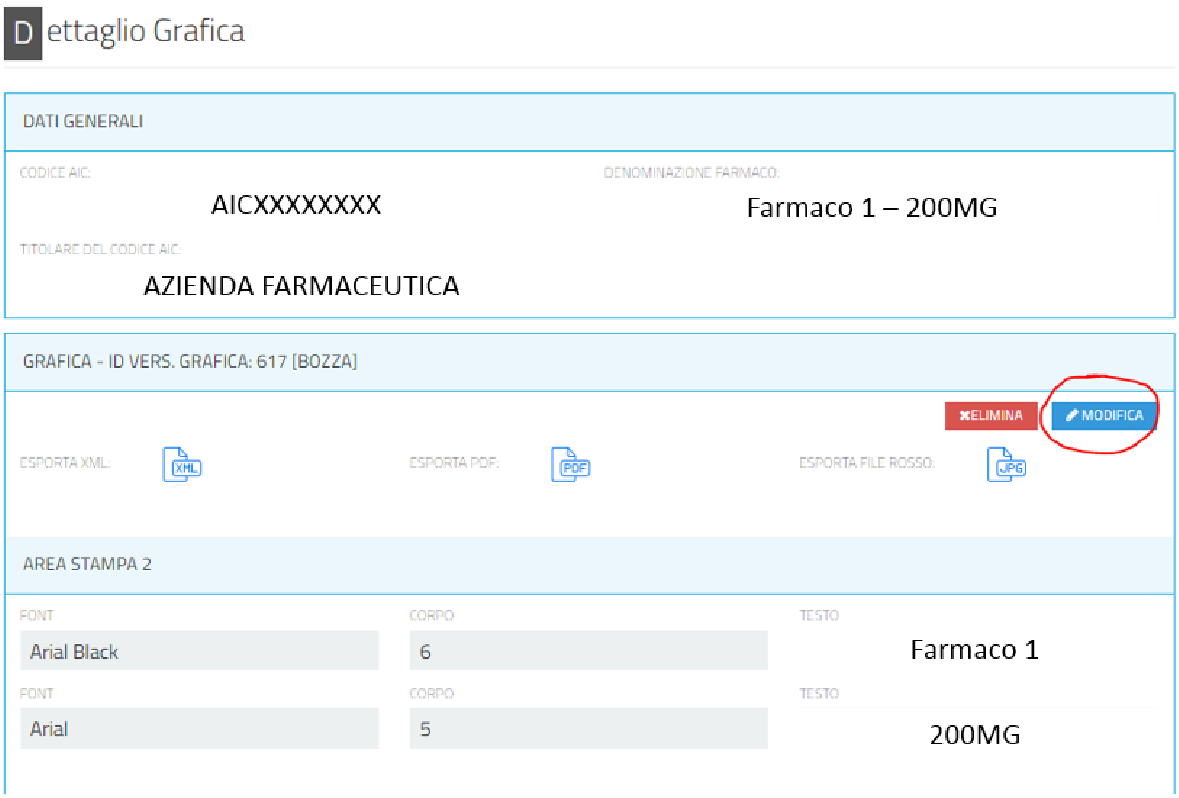
By clicking on CONFIRM the system performs a validation of data entered, and if it presents the detail page with the summary data.
The new graphics will be visible in the catalog but will not be purchasable until the option is activated.

8.2 Activate New Graphics

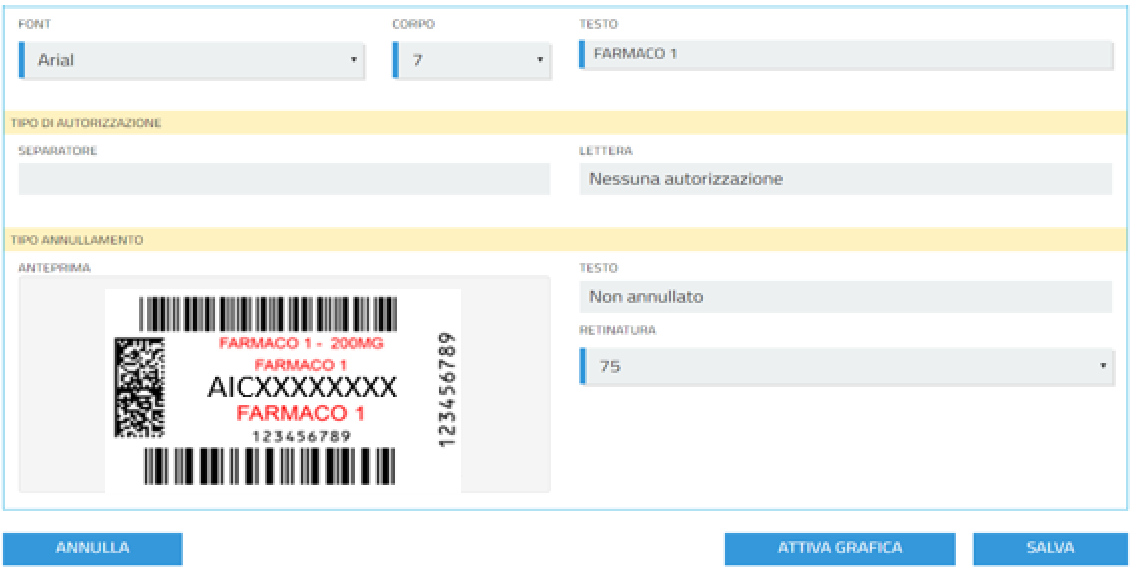
The new graphics will be visible in the catalog in "DRAFT" status.
To activate the new graphics select the AIC from the catalog and enter into "GRAPHICS DETAIL":



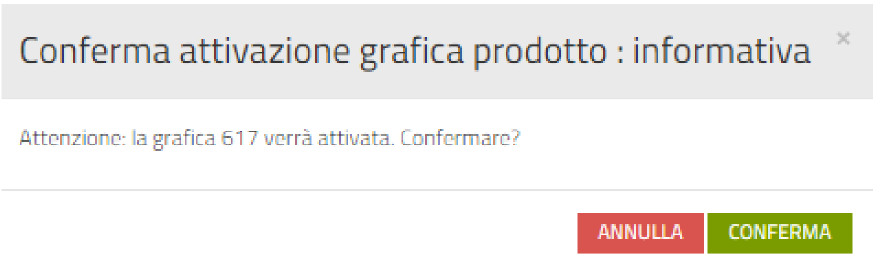
In Graphics Detail page you can view all the data previously entered



After pressing "Edit" button you will be able to access to data editing section where users can make changes or activate definitely the graphics in DRAFT state.



For activation you must press "ACTIVATE GRAPHICS"; the system will present the following confirmation message:



By pressing "CONFIRM" the system performs a validation of data entered and if positive it will presents the catalog page with the message confirming the transaction; by this time the new graphics can be purchased:

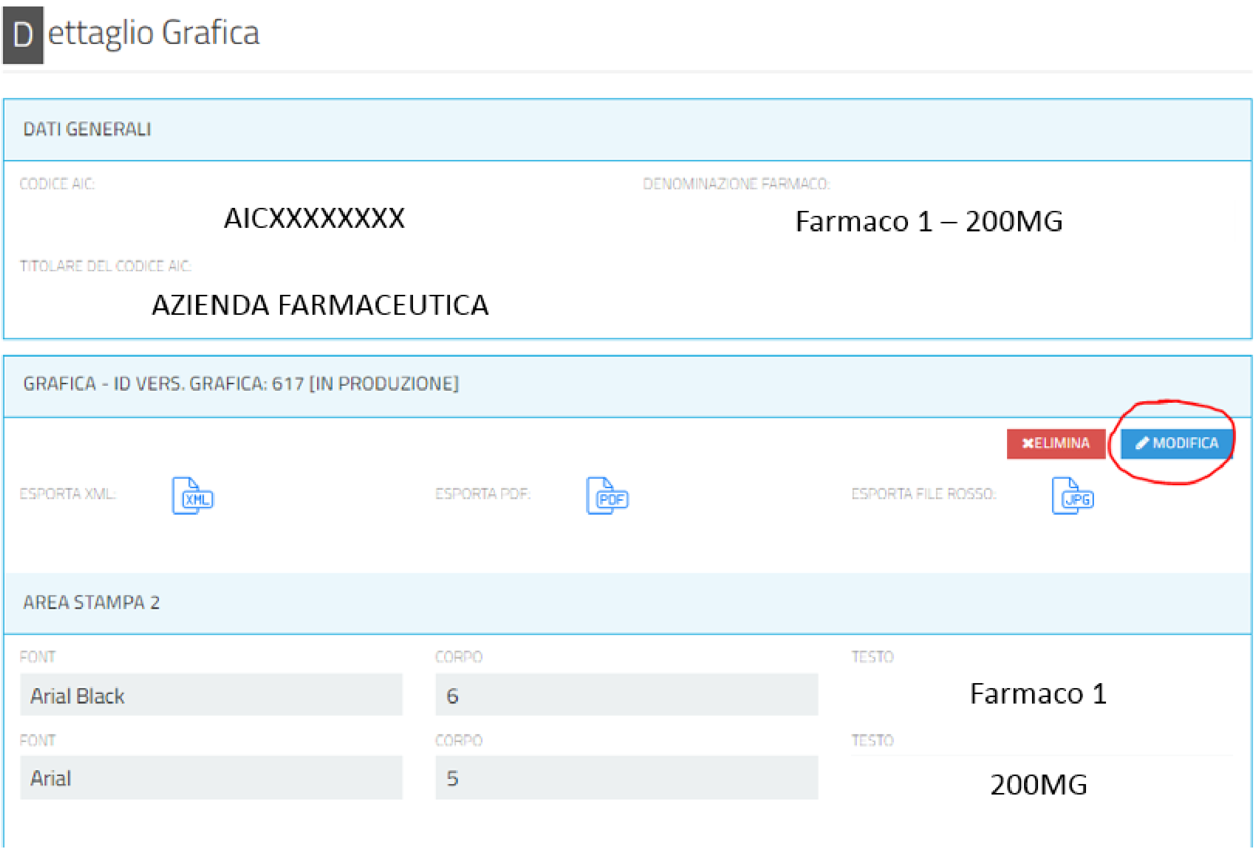
8.3 Edit active graphics

It is possible to upgrade a graphics using the "Edit" button present on the graphics detail page.

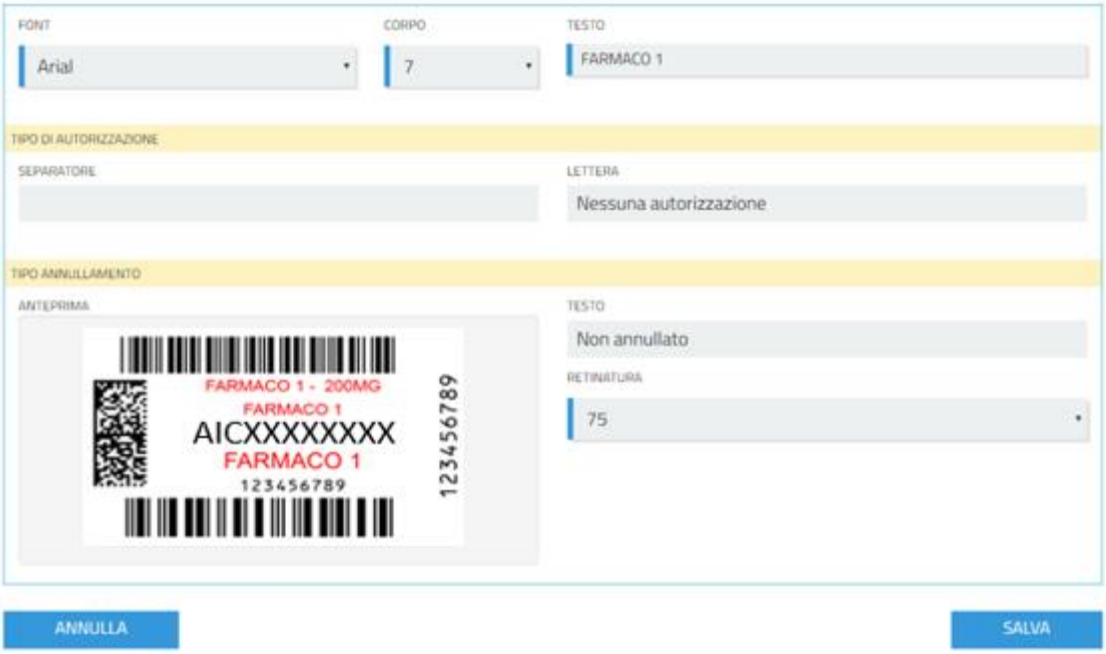
In this case the system displays an editable form that will update: data of the print area 2, data of the print area 4, data about the type of cancellation and the type of authorization (*AIC code fields, authorization code and cancellation type cannot be changed because they are the key of graphics).*

To access the capabilities of Edit, Select a graphics from the catalog and click on the "GRAPHICS DETAIL":

The page of "graphics detail" shows all the data related to the graphics itself. As shown in the image below, the graphics is active (IN PRODUCTION)



Pressing "Edit" button can change the graphics.

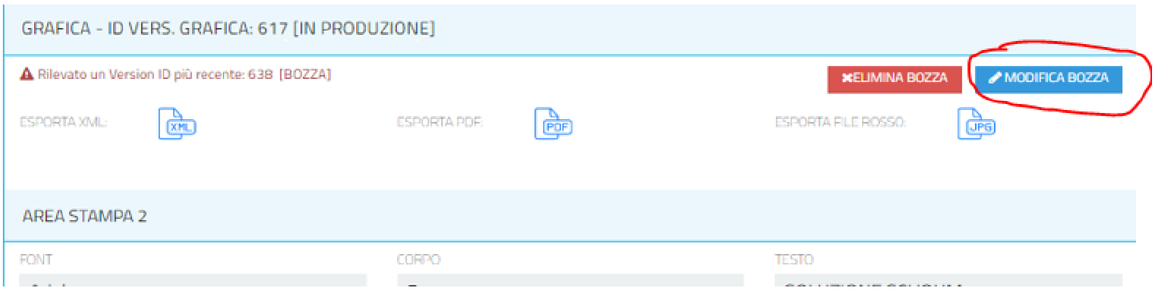


By pressing the "Save" button the system performs a validation of data entered, if positive it will show the graphics detail page just changed. The graphics you create will be in DRAFT state, therefore it won't be purchasable yet.

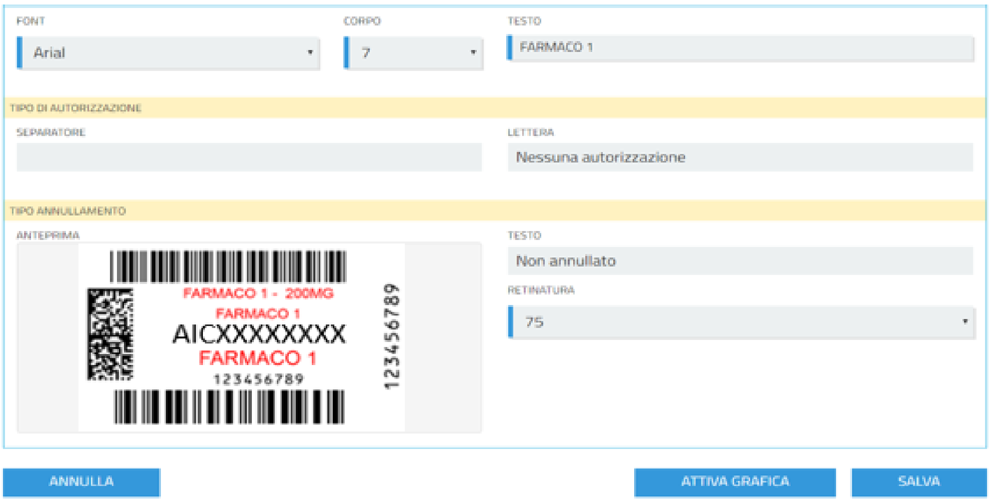
Selecting AIC from the catalog, the system will notify that it was "**Detected a graphics in draft State of the same type (Version ID xxxx)**". This will enable to understand to whom fills the orders that the personnel is producing a new graphics. For activation you need to enter the "graphics detail" and activate the graphics; in this case the new version will replace the previous, which will be in fact obsolete and no longer purchasable. *Caution: as described in paragraph 7, in case that there are one or more orders placed for IPZS containing the deleted graphics, these will be processed and produced normally, because activation of new graphics is after the confirmation of the order (containing the old one).*

Press "Graphics Detail"

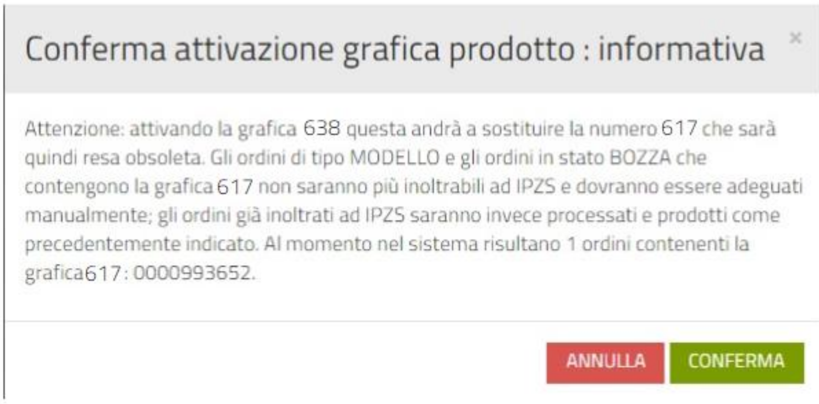
From the Graphics Detail page, click on "Edit Draft"



From the "Edit Graphics" page you can activate the graphics:



By clicking on the button "Enable Graphics" the system will present the following confirmation message:

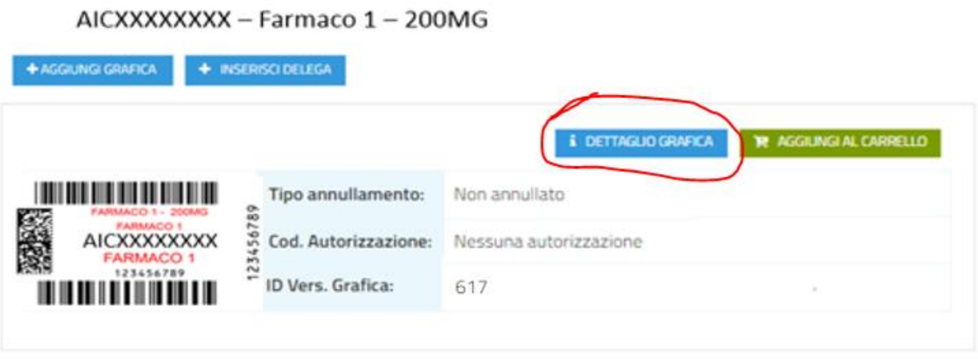


Clicking on CONFIRM the system performs a validation of data entered, if positive it will presents the catalog page and the new graphics could be sold.

8.4 Deleting Active graphics

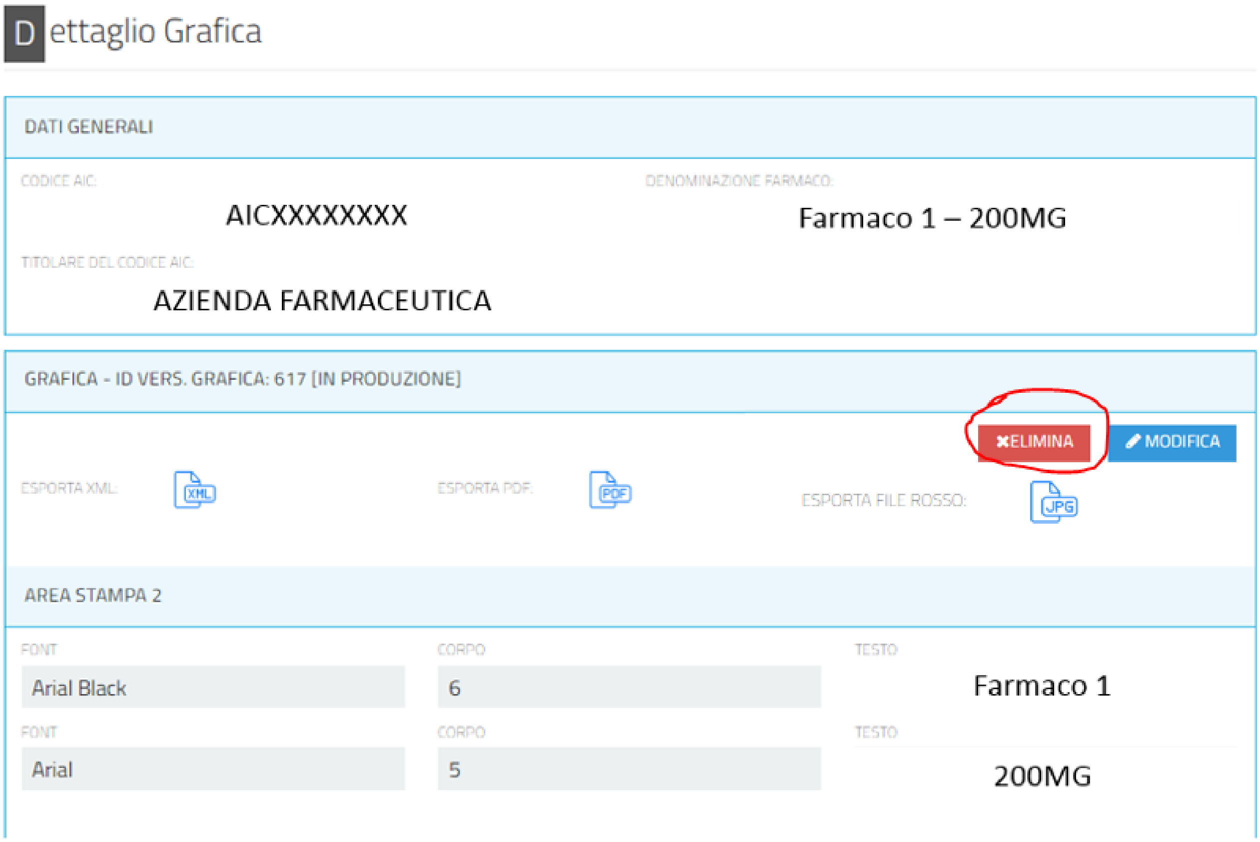
The deletion may be for a draft or active graphics (in production). Once deleted, the graphics will be no longer visible in the catalog. To delete an **active** graphics proceed as follows.

Select a graphics from the catalog and click on the "GRAPHICS DETAIL"

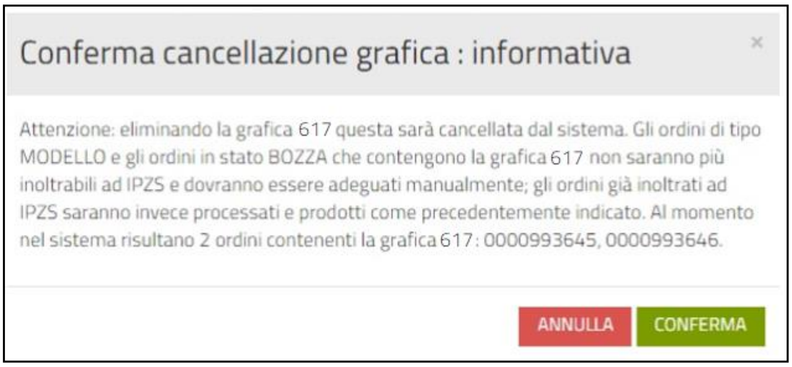


The page of "graphics detail" shows all the data related to the graphics itself.

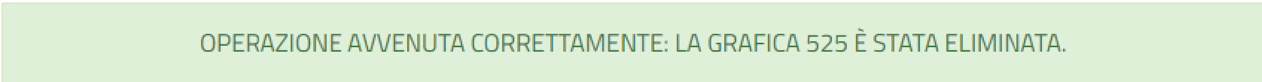
As shown in the image below, the graphics is active (IN PRODUCTION):



By pressing "DELETE" button the system will present the following confirmation message:



By pressing "confirm" the system returns the message of deletion:



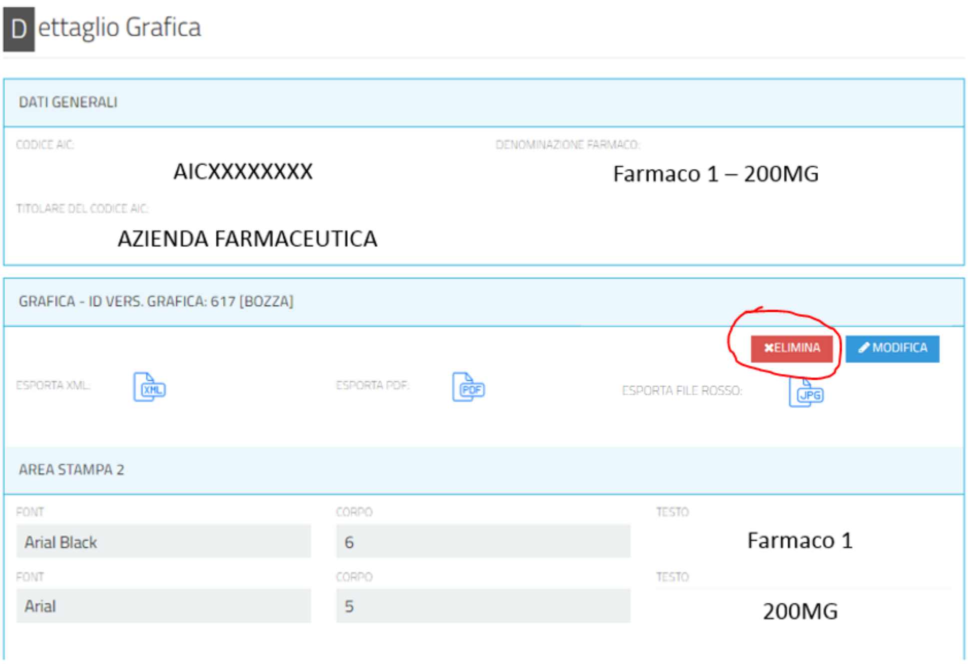
Warning: as described in paragraph 7, the graphics will be deleted and will no longer be purchased from the catalog. However the orders already forwarded towards IPZS, having just deleted graphics, will be produced normally.

8.5 Cancellation Graphics in Draft

To delete a draft Graphics Select the AIC from the catalog and enter the "GRAPHICS DETAIL":

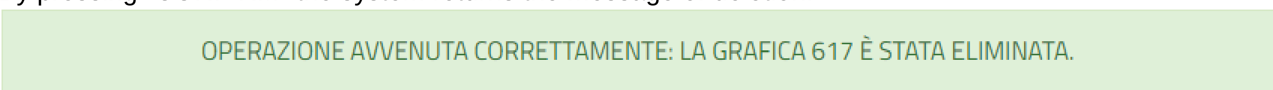
As shown in the image below, the graphics are in draft status:

Press the detail button to access the Graphics detail page where you can view all the data previously entered:



By pressing the "DELETE" key, the system returns the following confirmation message:

By pressing "CONFIRM" the system returns the message of deletion:



8.6 Detail graphics and export functions

From detail page of graphics, both active and drafts, you can also do the following:

<u>EXPORT XML FILE</u>

By pressing the button " EXPORT XML"

The system automatically downloads the XML file for selected graphic. The file name will be "**graphics_XXX**" where XXX is the ID of the graphics version.

<u>EXPORT PDF FILE</u>

By pressing the button "EXPORT PDF"

The system automatically downloads the PDF files for the selected graphic. The file name will be "**stamp_XXX**" where XXX is the ID of the graphics version.

<u>EXPORT RED FILE</u>

Pressing on "EXPORT FILE RED"

The system automatically downloads the image with extension "png" of fixed parameters of the label relative to the selected graphics. The file name is "**label_red_file_XXX**" where XXX is the ID of the graphics version.

9 ORDER PROCESSING

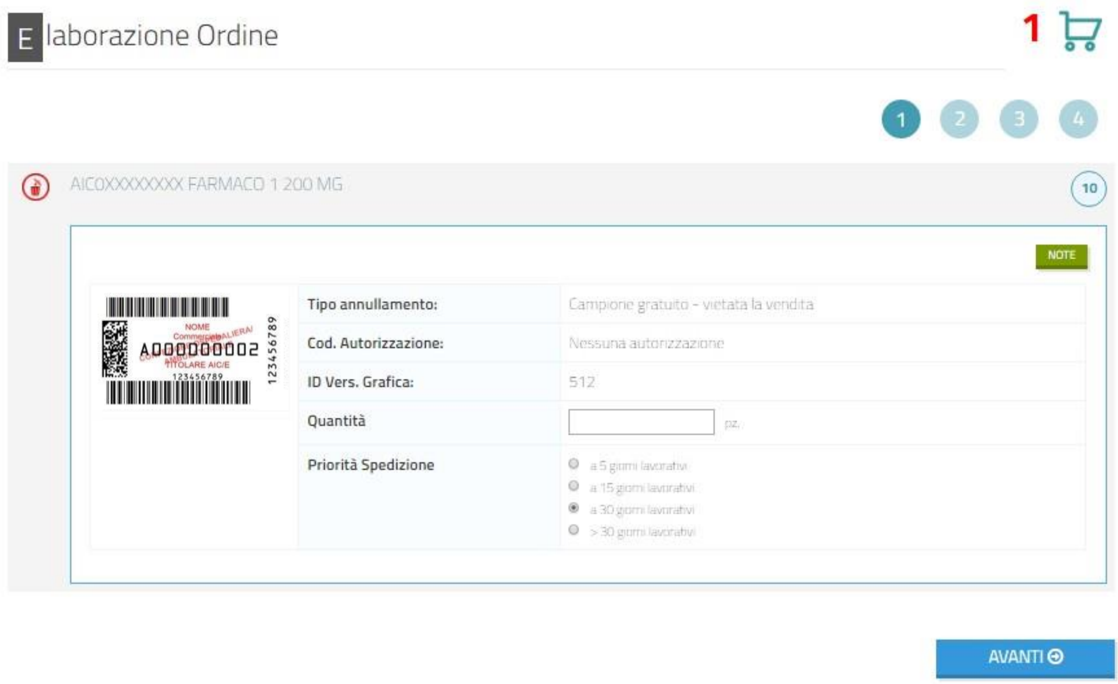
By clicking on the basket icon (containing the products chosen previously) the procedure to process the order is carried out in four distinct steps; this page is laid out as follows:

At the top right, the basket icon is visible with the number of products chosen by the User, and just below it are the four steps that Users must complete before saving. The next paragraphs describe the four processing steps in detail.

9.1 STEP 1

Step 1 displays (per line) the products added by the User to the basket, giving the possibility of removing a product from the basket (Trash icon to the left of the line), showing details of the item and allowing entry of:

- Desired quantity
- Delivery priority level
- User Notes (optional)

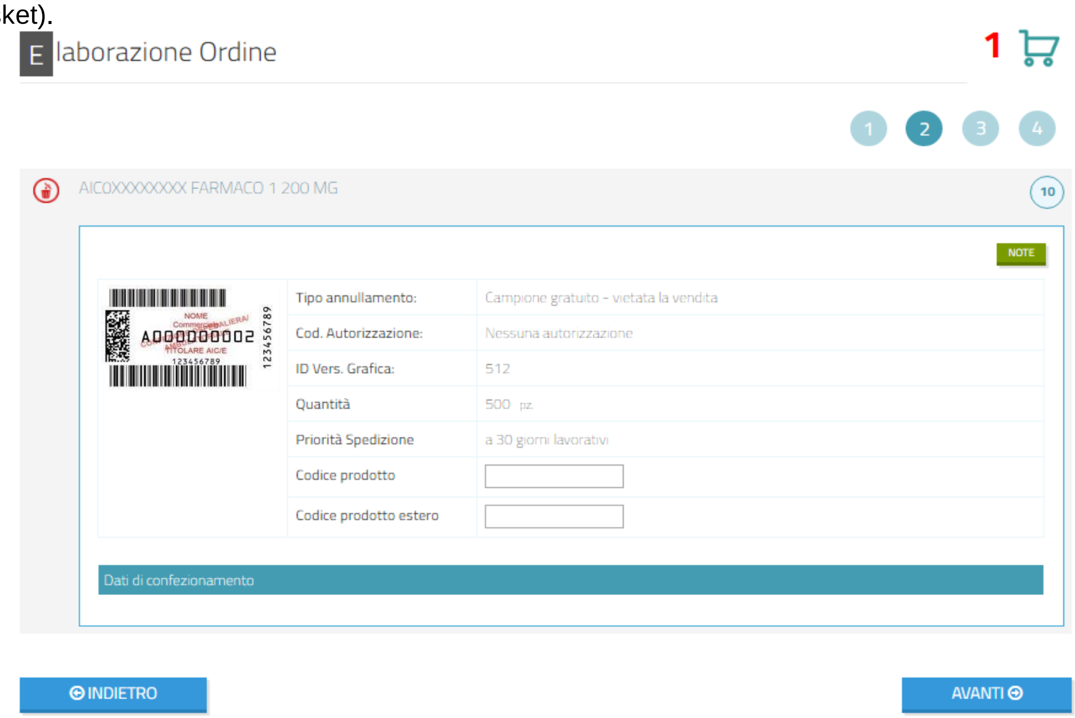


Clicking on the Note icon opens an additional field for User Notes (max. 255 characters). By clicking on the Trash icon, the system removes the chosen item from the basket, but first asking the User for a definitive confirmation.

Clicking on CONTINUE > accesses STEP 2 of the order procedure. N.B.: on clicking, the system verifies the data entered, according to the circumstances: Step 2 will not appear if there are inconsistencies in the data entered in Step 1 (e.g. non-numeric values in the Quantity field), and specific error messages will be displayed.

9.2 STEP 2

Step 2 is for the entering of packaging data and company references for every line of the order (i.e. for every item in the basket).



The company references are two input fields denominated *Product Code* and *Foreign Product Code*, while the packaging data are entered in a dedicated area that can be shrunk or expanded with a click of the mouse (closed by default). The Note icon serves to display the User Notes: by clicking on this icon, the text area will reopen (as read-only) with the notes added in Step 1.

The packaging data are structured as follows:

It is then necessary to state:

- <u>Number of labels per roll</u>
- **<u>Maximum diameter of roll</u>** (value calculated automatically by the system)
- **<u>Core diameter</u>** (constant value laid down in the General Supply Conditions)
- <u>Number of numbered sample labels</u>
- **<u>Position of boxes</u>**
  - low numbers below, high above
  - high numbers below, low above
- <u>Max. pallet height</u>

Packing requirements will automatically be calculeted by the system.

Clicking on CONTINUE > accesses STEP 3 of the order procedure. N.B.: on clicking, the system verifies the data entered; Step 3 will not appear if there are inconsistencies in the data entered in Step 2, and specific error messages will be displayed.

9.2.1 Standard Packaging and Reset

At the top right in the box with the packaging data is a button *Standard Pack* to set default values in the following fields:

FIELD NAME	STANDARD VALUE
Number of labels per roll	*10,000*
Packaging	*complete (three small in one large)*
Number of numbered sample labels	*0*
Position of boxes	*Low numbers below, high above*
Max. pallet height	*120 cm*

Instead, the *Reset* button clears the fields of the values entered by the User (manually, or by using the *Standard Pack* button).

9.3 STEP 3

Step 3 is to indicate the goods consignee for every product. The information entered previously will still be available as read-only. The Goods Consignee section allows selection from the company list of consignees using a Combobox containing: the name of the consignee company linked to the Town/City field linked to a specific name entered by the User on registering the consignee (see below):

Consignee Pharmaceutical Company: Example, Rome – Logistics 1

name — town/city — specific name

Selection of a consignee – if already present – will compile all the fields of the consignee displayed in letters only in the Goods Consignee section:

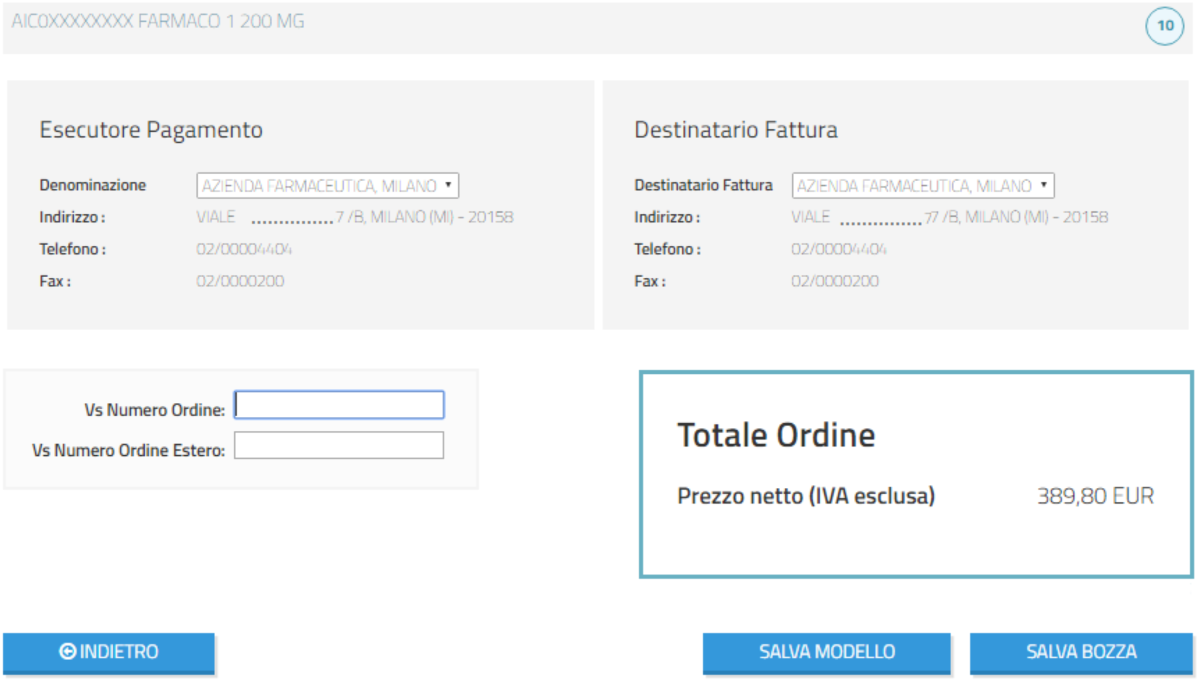
The button *Apply to All* assigns the selected Goods Consignee to all the lines of the order.

Note:
When entering order the default goods recipient field is empty. You can save it in draft, but at the time of ordering you must select the desired goods recipient.

9.4 STEP 4

Step 4 consists in summarizing the order where Users can check the data entered at every position. On the summary page, all the sections referring to positions are in letters only with the exception of the following fields:

- *Your Order Number (always displayed and optional)*
- *Your Foreign Order Number (always displayed and optional)*
- *Selection of Invoice Addressee*
- *Selection of Payer*

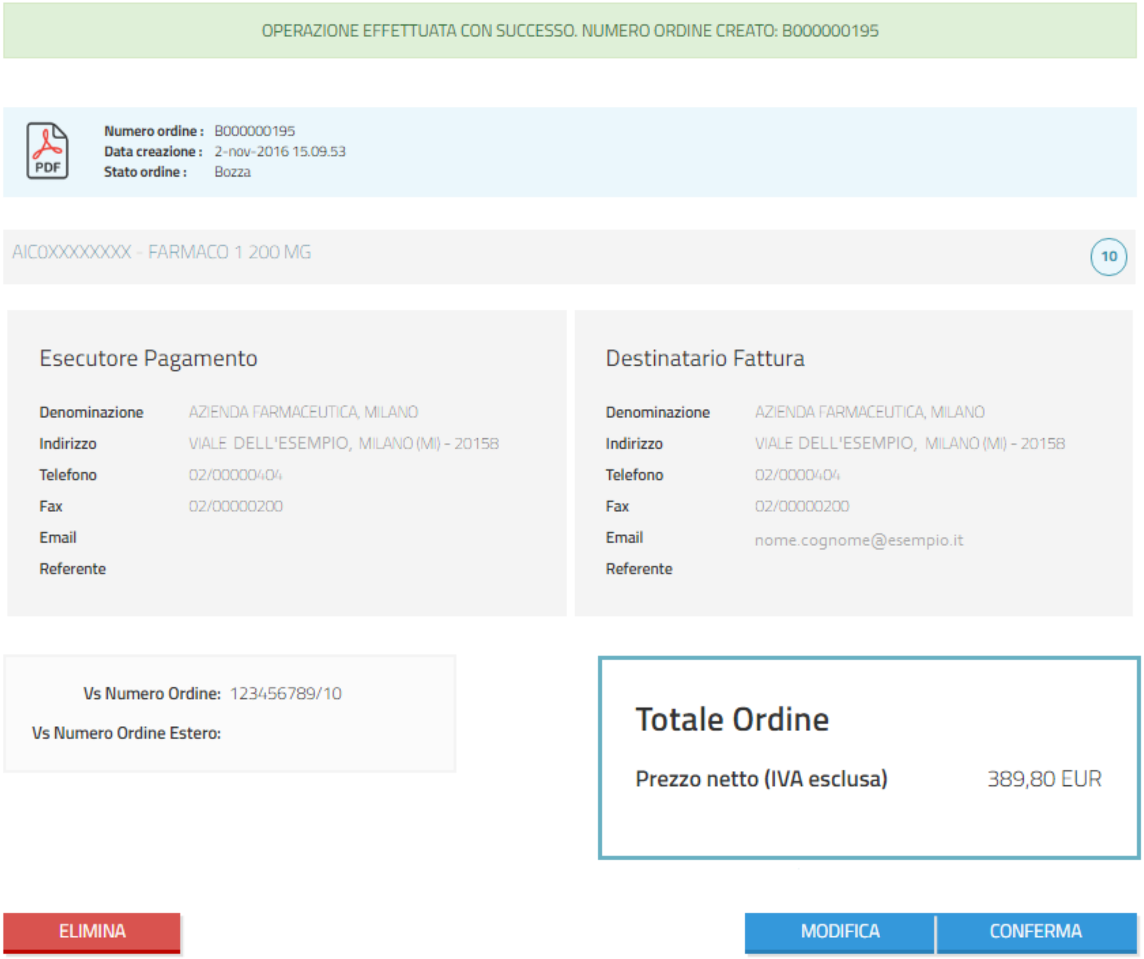


In this phase, the system calculates the amounts of the order both per position (partial) and per order in the Order Total section. The User can decide whether to save the order as a draft or as a model (see relevant sections).

9.5 Draft

By clicking on Save Draft, the order is saved in the system but is not sent to IPZS. The Customer can make all the alterations they like – to every section of the order – and send it to IPZS only when they are completely certain of all the data entered.

When the order is saved, the system will provide the User with an order number (for drafts, the system generates specific numbering: a unique 9-digit numeric code preceded by the letter B), a time and date stamp, the status, and a link to download the order summary in PDF format:



The order will now be available in the Last 5 Orders section or can be traced using the Order Search function (see relevant section). Following the saving of the order, on the Operation Completed page, we can find the following three buttons:

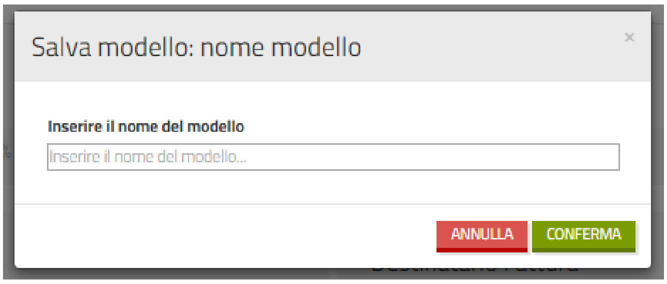
- Eliminate Order: to eliminate the order from the system (possible only for drafts)
- Change Order: to change the data entered if there are errors or gaps
- Confirm Order: to definitively approve the order and send it to IPZS.

9.6 Model

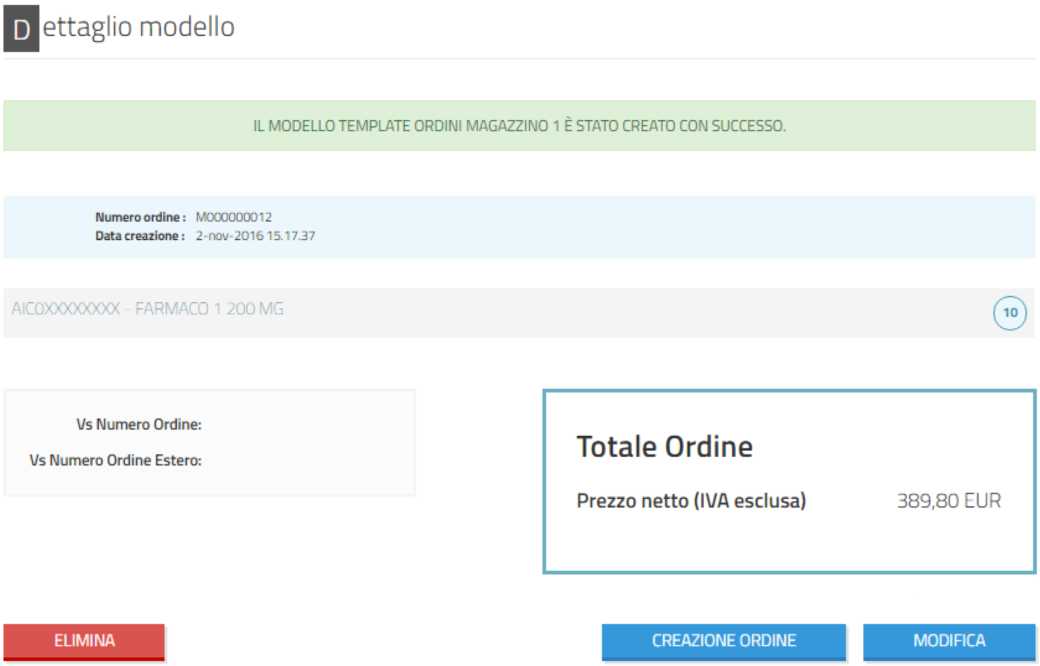
Saving the order as a model (or reference order), allows Users to create reference templates for subsequent orders; an order model will never be sent to IPZS, but will be used to map the basic characteristics of sales orders that will then be generated by calling up a model. The mandatory data set to save an order model is minimal and consists exclusively in choosing products that the order should contain plus the name of the model (which will serve to call it up subsequently).

The quantities, shipping methods, packaging data, goods consignee, invoice addressee and company references are all optional data that can be specified later (e.g. Order Generation).

Therefore, on saving the model, the system will ask the User through a modal dialogue window, to enter the name of the model (e.g. *Warehouse Orders Template 1*):



as confirmation, it will display the following message:



The system also generates specific numbering for models: a unique 9-digit numeric code preceded by the letter M.

The buttons available for this step are:

- Eliminate: to definitively eliminate the order model from the system.
- Create Order: to generate an actual order from the model
- Change: to change the data in the model

In any case, an order can be traced using Order Search (see relevant section).

9.7 Changing an Order

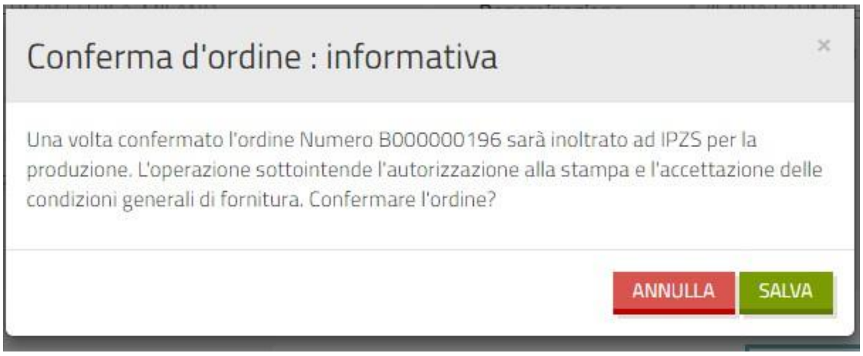
By clicking on CHANGE (available for Draft orders and Models) the order will be reopened and the 4 steps seen previously will again be available to modify the sections in question; please note that the Step numbers at the top right are clickable to navigate more easily inside the order to be modified.

To confirm the changes, Users must proceed – using either standard navigation, or direct access – to Step 4, where it is possible to:

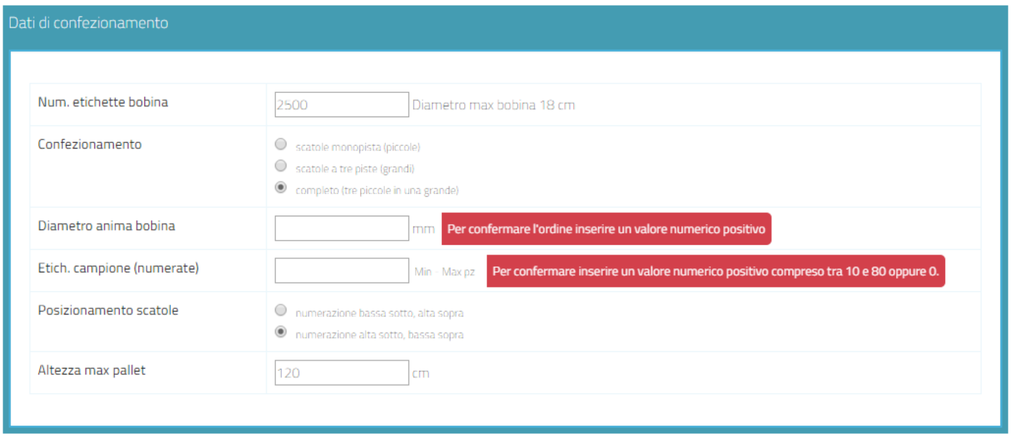
- Save again as a Draft
- Confirm the order
- Eliminate the order

9.8 Order Confirmation

Order Confirmation is the operation that sends the sales order to IPZS. Therefore, by clicking on CONFIRM, the system will display the following information:

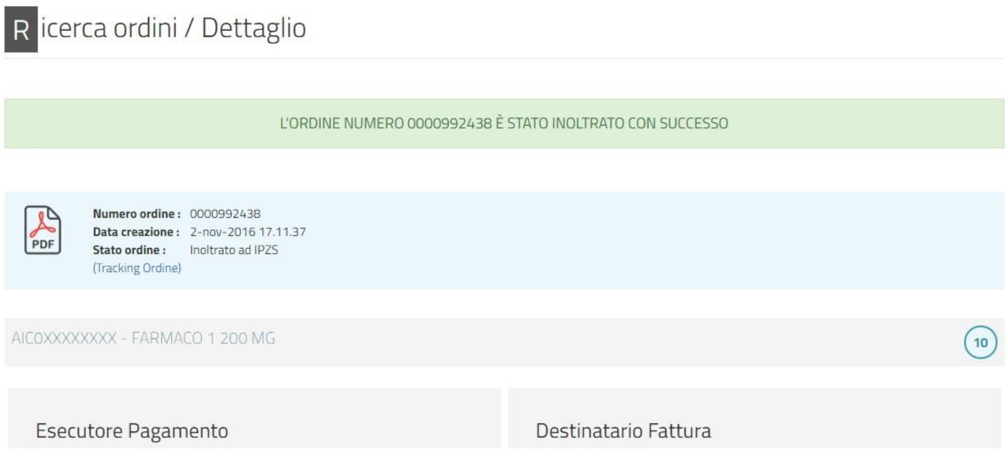


By clicking on SAVE, a complete validation of the order data is made; below is an example where the system takes Users to Step 2, communicating any gaps in the packaging data:

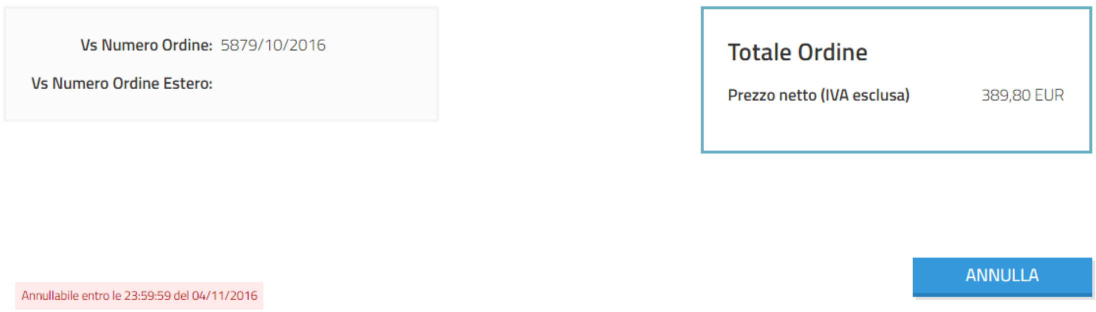


Once the information has been corrected, and the order has again been saved, Users can re-access the page of details and again click Confirm. As soon as an order has been sent, the system will replace the Draft numbering with a definitive one that will unequivocally identify the order throughout its life cycle; in addition, it will then be possible to track the status (see relevant section), to download an order summary with the latest updates, or to cancel the order.

N.B.: for positions where shipping has been set for more than 30 working days (> 30 working days), upon confirmation, the system will ask the User to validate the Shipping Date.



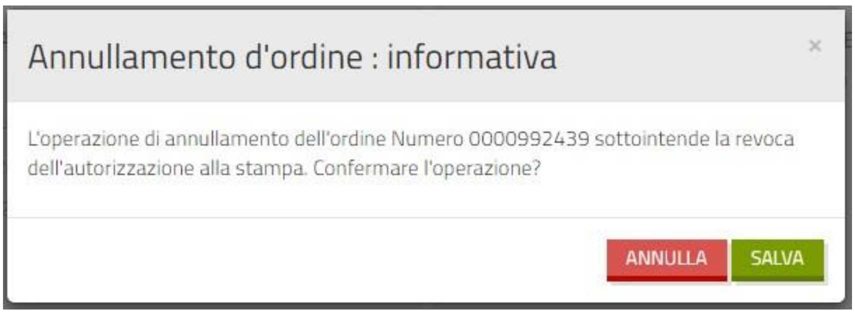
Orders may be cancelled within a timeframe calculated automatically by the system (for details on validation timeframes please see the General Supply Conditions), which appears beside the CANCEL ORDER button in any case.



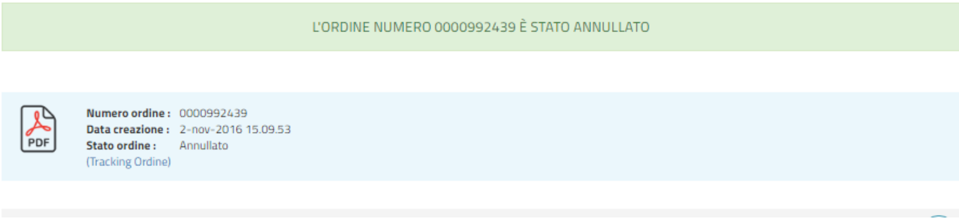
9.9 Deleting an Order

Orders may be cancelled exclusively within a certain timeframe (for details on validation timeframes please see the General Supply Conditions) within which it is frozen while IPZS production planning may have begun. Beside the CANCEL ORDER button, the last date for validation is always shown; instead when the order has been frozen, the CANCEL button will no longer be visible.

Clicking on the CANCEL ORDER button (when active), will bring up the following message:



Clicking on the SAVE button will bring up the message “Operation Completed”:



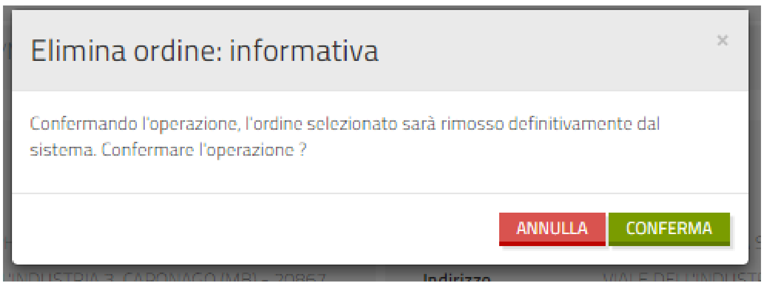
9.10 Copying an Order

For cancelled orders, there is a “copy” function, that makes it possible to create a new order starting from a copy of one that has been cancelled. The COPY ORDER button is available – only for cancelled orders – at the foot of the page under the Total box:

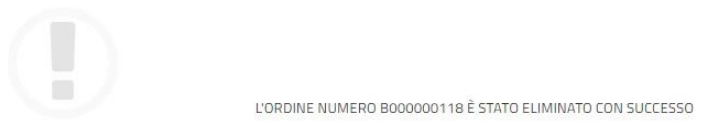
Clicking on COPY ORDER opens the procedure to create an order – Step 1 – from the data of the cancelled order memorized previously; here Users can make any alterations they like without having to start from a “blank sheet”.

9.11 Delete an Order

Clicking the DELETE button, available only for Draft orders or Models, brings up the following system message:

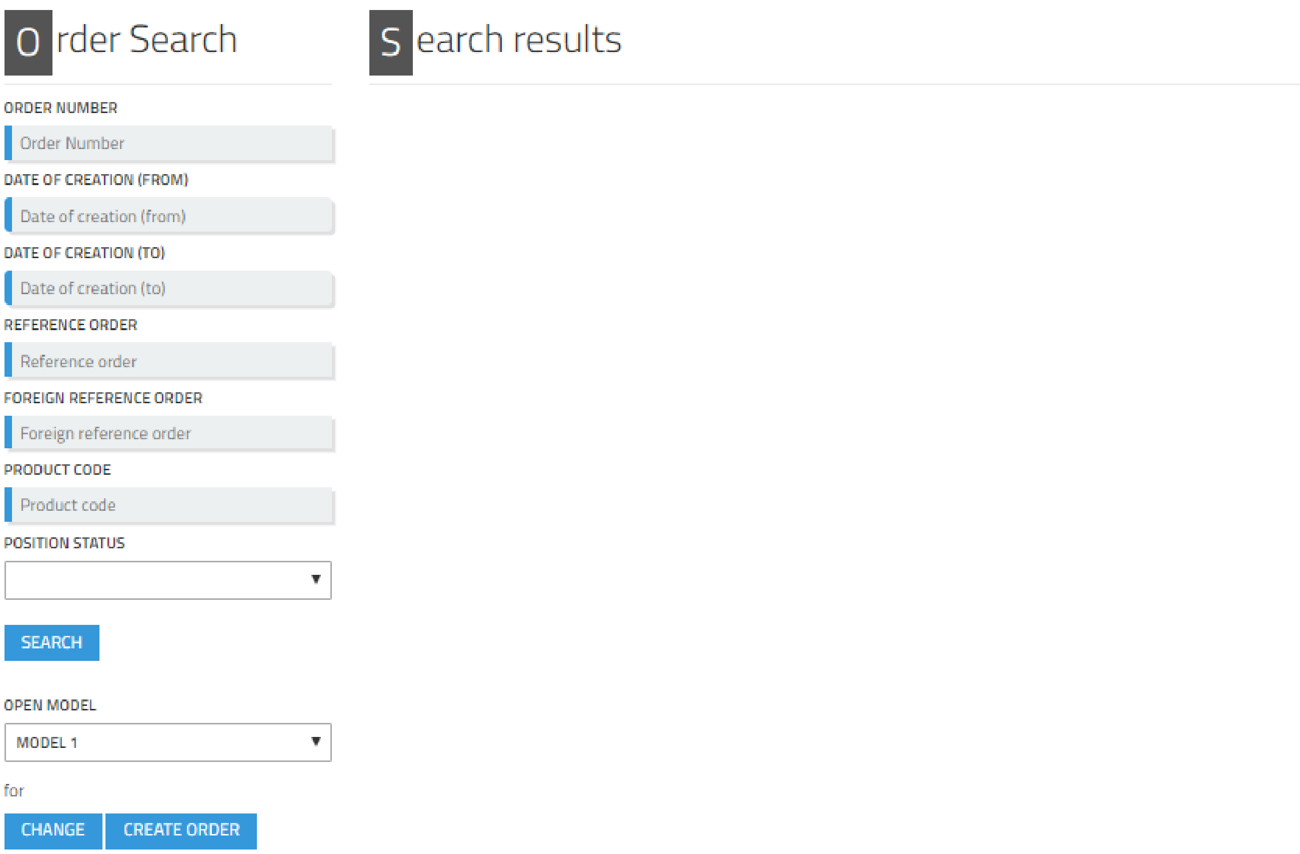


Upon confirming the operation, we see the following video message:



10 ORDER SEARCH

This function makes it possible to navigate through the pharmaceutical company's archive and search among all the orders entered in the system; clicking on Order Search on the Main Menu will bring up a page laid out as follows:



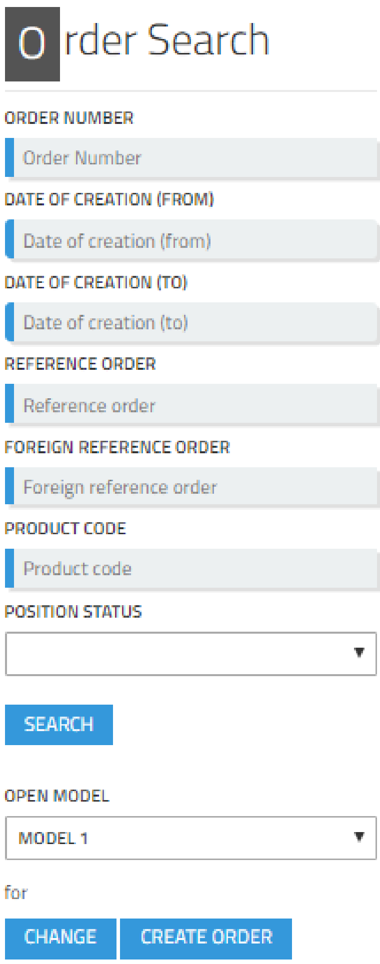
10.1 Form of Search

The Search area shows the following input fields:

- Order Number: input field to contain the desired order number
- Date of creation (from): data field
- Data of creation (to): data field
- Reference Order: input field to contain the reference order number of the associated order

- Foreign Reference Order: Reference Order: input field to contain the reference order number of the associated foreign order
- Product Code: input field to contain the AIC Code ordered
- Order position status: input field to contain the Status of the order position

There is also a subsection to directly open models both to change them and to generate an order:



By compiling at least one field, and clicking on the Search button the system will search through the Customer's archive and will display the results in the relevant section (see next paragraph).

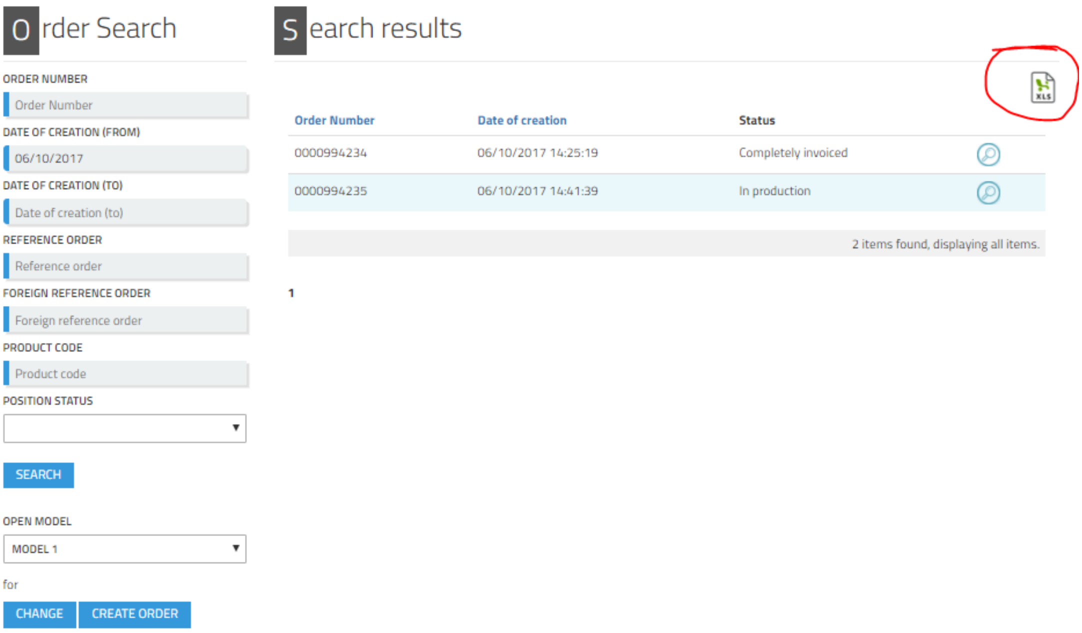
Instead, a model can be called up for changes (to alter the information based on the template), or to create an order, i.e. a new sales order based on the template selected.

10.2 Results Found

This section shows as a table the results answering the search criteria used; for each order found the following information is shown:

- Order number
- Date of creation
- Status

In addition, it is possible to reopen the order and to proceed with the processing workflow, based on the order status and the User profile:



By clicking on the highlighted button, you can download Excel's list of order positions extracted in the search.

10.3 Details and Tracking

Clicking on the order number after a search or on the boxes of the homepage for orders, the system will reopen the details of the order; based on the status, certain buttons and functions will then appear. E.g. the Eliminate button will appear only if the order is still a draft, while Order Tracking (and its positions) is available only for orders whose status is at least *Sent to IPZS*. Below is a list of statuses referring to sales orders:

DRAFT
The order has been made, it features a temporary order number, it can still be modified by the company, but is not yet visible to IPZS.

SENT
The order (**and all its positions**) has been approved by the company and sent to IPZS: the sending step replaces the communication of the Imprimatur. An order that has been sent has a definitive numbering and may be cancelled according to the terms laid down in the General Supply Conditions.

CONFIRMED
This is the status of the order when one or more positions have been confirmed by IPZS; i.e. production planning has been made for the positions processed. N.B.: when a position enters this status, the system will automatically notify the User of the progress via an automatically generated e-mail.

CANCELLED
The order (**and all its positions**) enters this status when cancelled by the User. Cancellation can be made exclusively in the ways laid down in the General Supply Conditions.

COMPLETELY SENT
When all the lines of the order show Sent (some may even have been invoiced, but the status will still be Completely Sent).

COMPLETELY INVOICED
The order enters this status when all the positions have reached the Invoiced status (after an invoice a credit note can be issued, however, the status remains Completely Invoiced).

Then there are statuses that will only be visible at the position level and that may provide further indications on the processing status.

10.4 Tracking Shipping Italy

For orders with delivery to ITALY will display the following status:

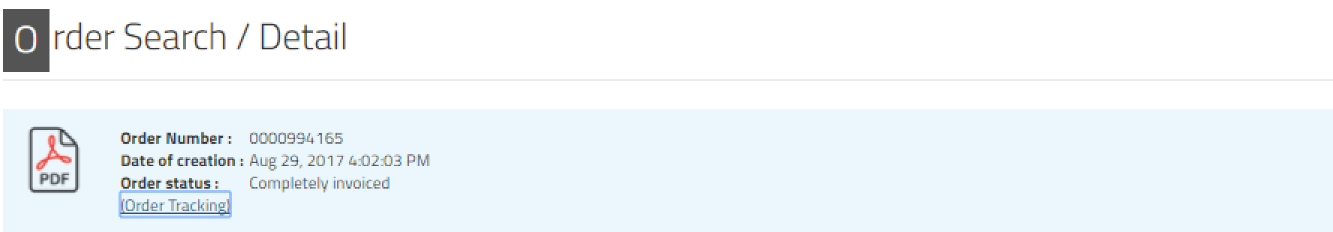
POSITION OF ORDER IN PRODUCTION
The specific position is in the production line.

POSITION OF ORDER SENT
The order line enters this status when goods have been prepared for shipping. At this status, you will be able to download the "Bolla di Consegna" document that reports useful logistical information to the customer.

Status	Data status	Documents
Sent to IPZS	29/08/2017 16:02:07	
Confirmed by IPZS (Roma)	29/08/2017 16:03:06	
In production	29/08/2017 16:08:29	
Sent	29/08/2017 16:09:46	PDF

POSITION OF ORDER INVOICED
The order line enters this status when the IPZS administration has issued an invoice.

Thus, for sent orders, details of the order status progress (and its positions) can be seen by clicking on the TRACKING link near the current order status:



Details are given below of the statuses that can be seen by clicking on the label (Order Tracking):

Detail of Order Status

Order Number: 0000994165

Status	Data status	Documents
Created	29/08/2017 16:02:03	
Sent to IPZS	29/08/2017 16:02:07	
Confirmed by IPZS	29/08/2017 16:03:06	

AICOXXXXXXXX - FARMACO 1 200 MG (10)

Status	Data status	Documents
Sent to IPZS	29/08/2017 16:02:07	
Confirmed by IPZS (Roma)	29/08/2017 16:03:06	
In production	29/08/2017 16:08:29	
Sent	29/08/2017 16:09:46	PDF
Invoiced	29/08/2017 18:55:43	

Therefore, for every position, the system will display the entire processing status for a product right up to the invoicing.

Note:

Each status update will be notified via email to the author your Order.

10.5 Tracking shipping abroad

In order to provide more detailed tracking, additional statuses have been introduced that will only be visible for Orders with delivery outside the Italian territory. Furthermore each status update will be notified via email to the author your Order.

For orders shipped abroad will display the following status:

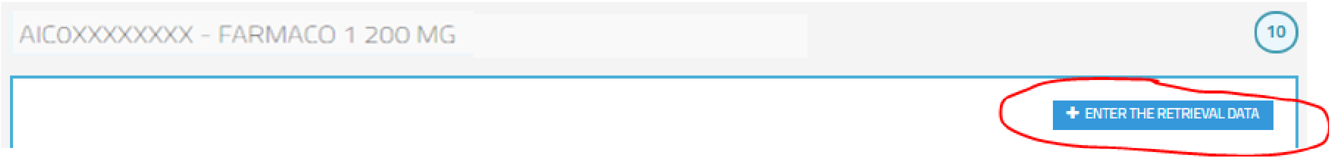
POSITION OF ORDER IN PRODUCTION
The specific position is in the production line.

POSITION OF ORDER AVAILABLE IPZS
The order line acquires this status when the goods are available for withdrawal at the IPZS production site (Rome or Foggia). In this status, you will be able to download the "Bolla di Consegna" document that contains the

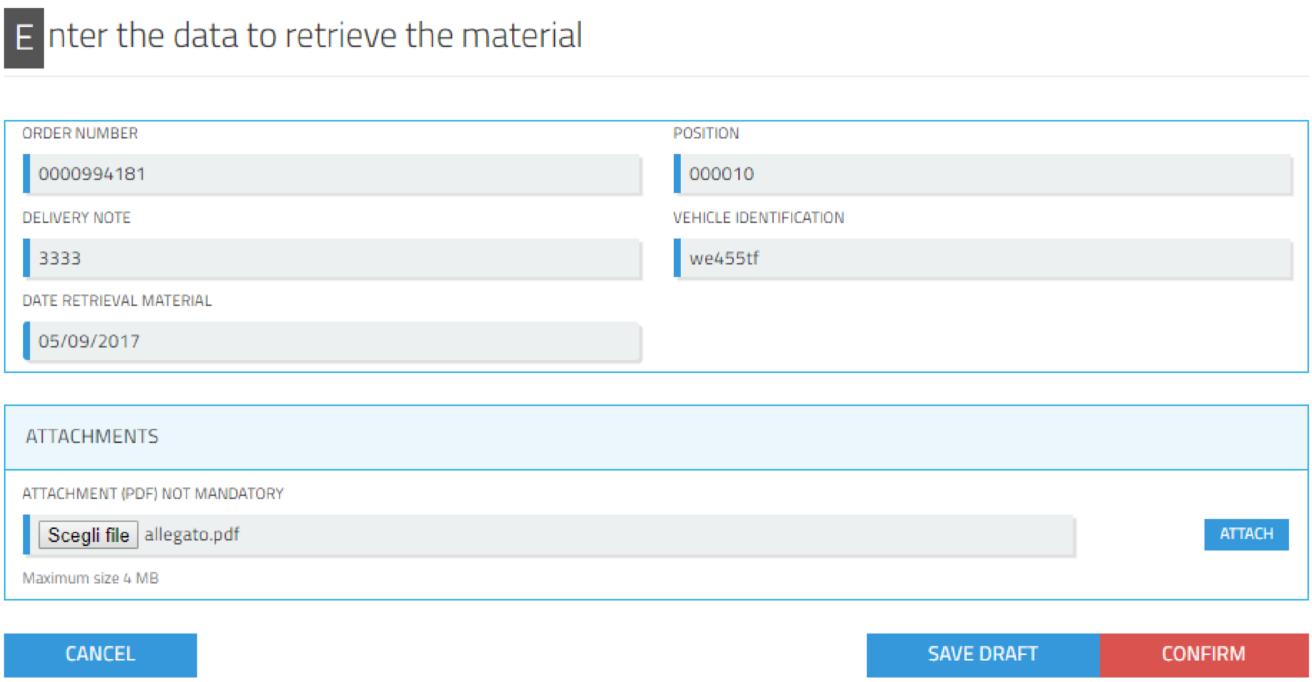
customer's information to arrange the withdrawal of the goods (Shipping Address, Number of Holes, Weight, ect ...).

Status	Data status	Documents
Sent to IPZS	01/09/2017 16:29:56	
Confirmed by IPZS (Roma)	01/09/2017 16:31:06	
In production	01/09/2017 16:32:00	
Available IPZS	01/09/2017 16:32:47	PDF

The withdrawal of the goods can be managed through a form accessible from the detail page by clicking on the "ENTER THE RETRIEVAL DATA" button.



The user can save the data in draft or confirm it definitively.

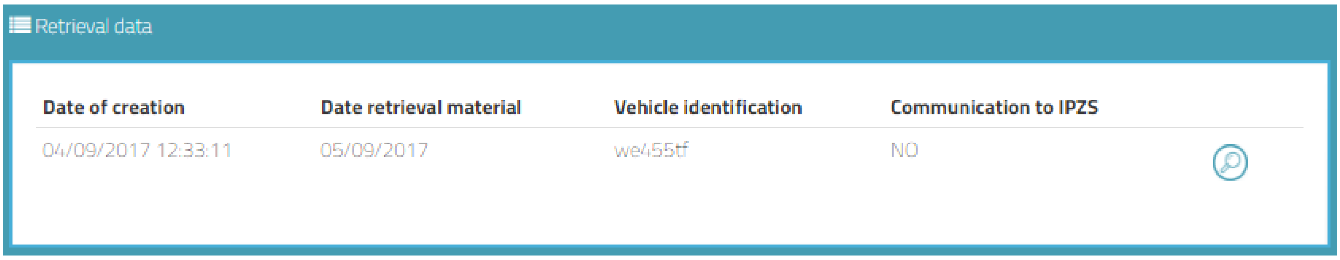


The information to be entered are:

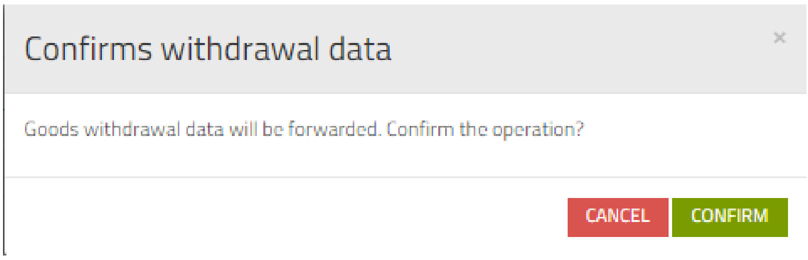
- Delivery Note: is tha waybill number (not mandatory)
- Vehicle Identification (not mandatory)
- Data retrieval material: is the date when IPZS is required to prepaire the goods for withdrawal (MANDATORY)
- Attachment: you can insert an attachment in PDF format that will be sent to IPZS (not mandatory)

By pressing "SAVE DRAFT" key will save the data to the Portal but will not be sent to IPZS.

The information entered will be visible on the detail page of the Order and may be modified until it is confirmed and then sent to IPZS.



By pressing "CONFIRM " key a pop-up will prompt you for confirmation:



By pressing "CONFIRM" key, the data will be sent to IPZS and will no longer be able to modify them.

Note: The goods can be picked up on the day following today's date, confirming the withdrawal by 13:00.

Once the information has been sent to IPZS, the status from the order's position will be transmitted from "Available at IPZS" to "Awaiting withdrawal".

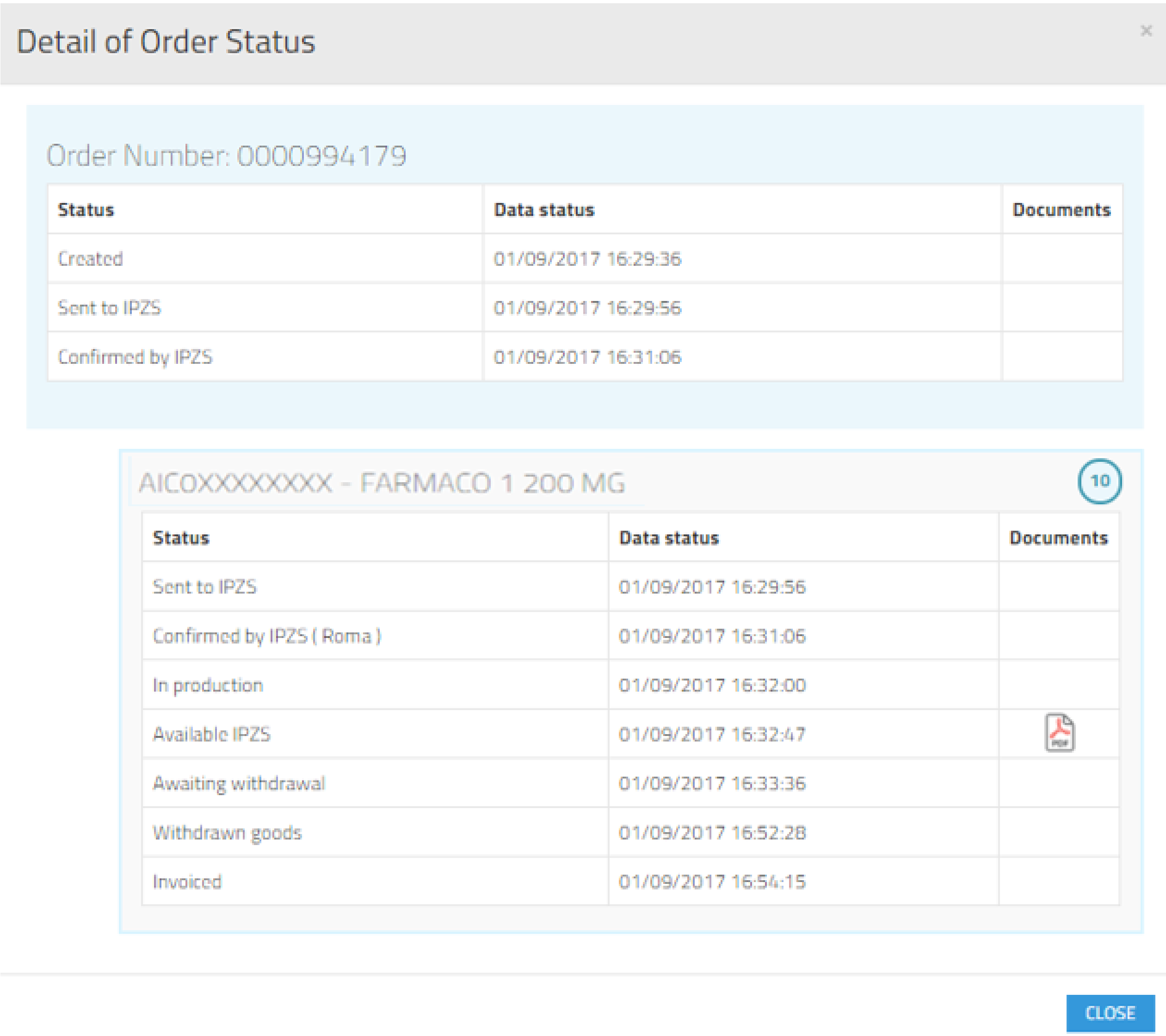
POSITION OF ORDER AWAITING WITHDRAWAL

The order line acquires this status when the customer has confirmed the withdrawal of the goods through the detail page by clicking on the "ENTER THE RETRIEVAL DATA" button. (see previous status)

POSITION OF ORDER WITHDRAWN GOODS
The order line acquires this status when the goods have been withdrawn at the IPZS (Rome or Foggia) production sites.

POSITION OF ORDER INVOICED
The order line enters this status when the IPZS administration has issued an invoice.

The following screen shows the available states for overseas Orders:



Detail of Order Status

Order Number: 0000994179

Status	Data status	Documents
Created	01/09/2017 16:29:36	
Sent to IPZS	01/09/2017 16:29:56	
Confirmed by IPZS	01/09/2017 16:31:06	

AICOXXXXXXXX - FARMACO 1 200 MG (10)

Status	Data status	Documents
Sent to IPZS	01/09/2017 16:29:56	
Confirmed by IPZS (Roma)	01/09/2017 16:31:06	
In production	01/09/2017 16:32:00	
Available IPZS	01/09/2017 16:32:47	PDF
Awaiting withdrawal	01/09/2017 16:33:36	
Withdrawn goods	01/09/2017 16:52:28	
Invoiced	01/09/2017 16:54:15	

CLOSE

11 COMMERCIAL DATA

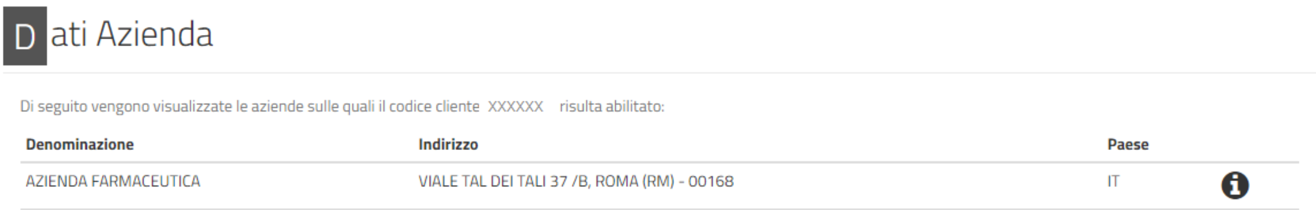
This section allows access to the function that manages the Customer's commercial data which are used during processing of orders generated by the Portal. Details are given of:

- Customer Company
- Goods Consignee
- Invoice Addressee
- Payer

The current version of the Portal (1.1) allows *Search* and *Display* of the above details. The next paragraphs will describe the ways to use the functions indicated.

11.1 Company Data

For every company that Users are authorized for, clicking on Company Data brings up the following information: Name, Address and Country:



Clicking on the icon ℹ will bring up the complete details on the Customer as shown below:

11.2 Search

Instead, clicking on *Search* opens the Search Section and shows details of the Customer Company's "business partners": goods consignees, invoice addressees, and payers. This section is divided into two parts: on the left-hand side we find the Form of Search, while on the right-hand side we find an area that contains the search results:

The search is guided by type: in fact, by expanding the dropdown menu we can find all the types of business partner that a Customer Company would normally have:

By selecting a type and clicking the Search button, the system will show the results found on the right, with the Name, Address and Country for each of them:

By clicking the Details icon it is possible to see complete details of the partner currently present in the system used to process orders:

The set of demographic data shown consists of:

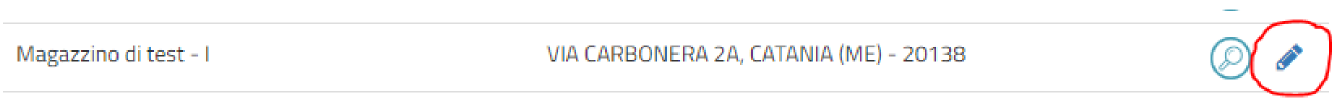
- Name of partner
- Address, no., town/city, post code, province/county and country
- Tax ID
- VAT No.
- IPA Code (public administration ID)
- Phone
- Fax
- PEC certified e-mail
- Standard e-mail
- Split payment (electronic invoicing for PA)

In case of a Goods Addressee the identify consist of:

- Name of the customer (company) in which it is hooked the consignee.
- name of the destination point
- address, street address, city, zip code, State and country
- Tax code
- VAT
- telephone
- Fax

11.3 Editing a Goods Consignee

By clicking on the icon is possible to modify the data of a Goods Consignee:



In the "Edit Goods Consignee" page the user can modify the following data page:

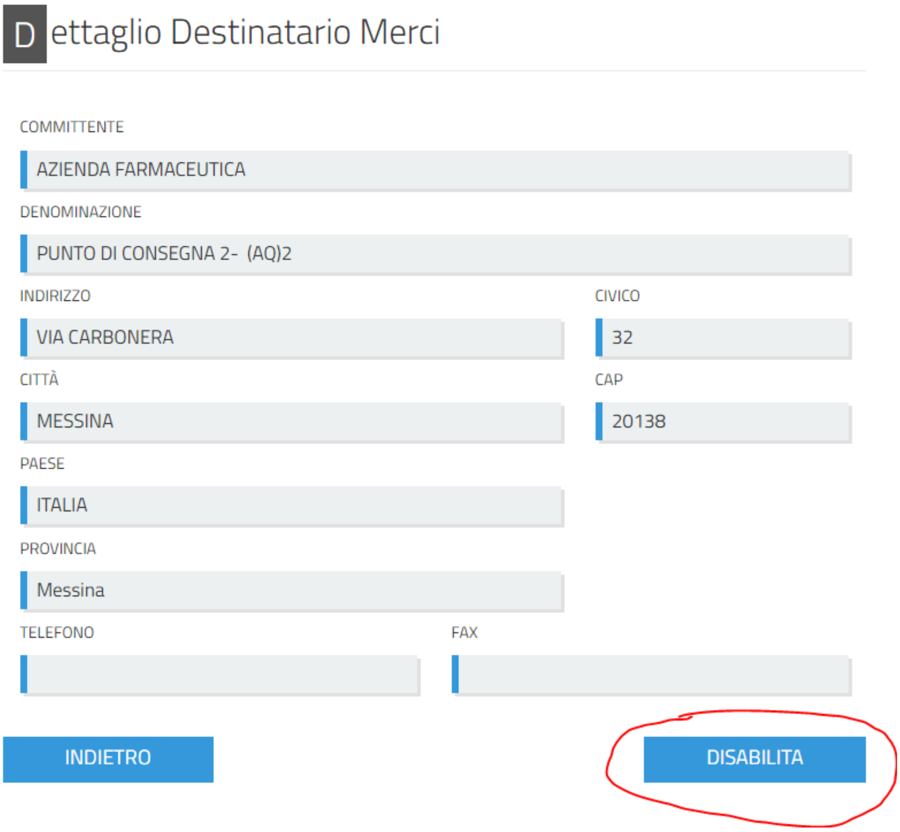
- Denominazione
- Address
- Street number
- City
- Postal code (ZIP Code)
- Province
- Telephone
- Fax

To save the modified data click on the "SAVE" button, and confirm the operation:

If the user presses the "Confirm" button, the system returns the message of the successful operation.

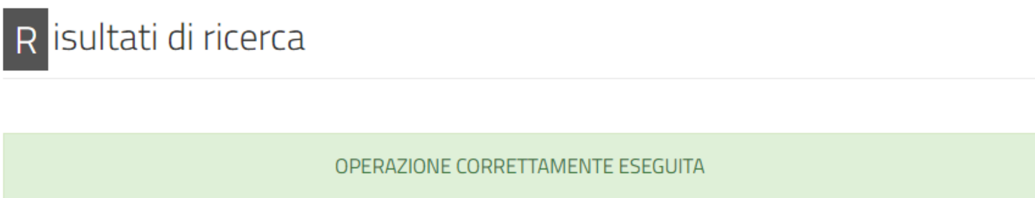
11.3.1 Disabling a Goods Consignee

Within the "Detail Goods Consignee" you can also "DISABLE" a Consignee that is no longer used by the company by clicking on "DISABLE" button:



You will need to confirm the operation:

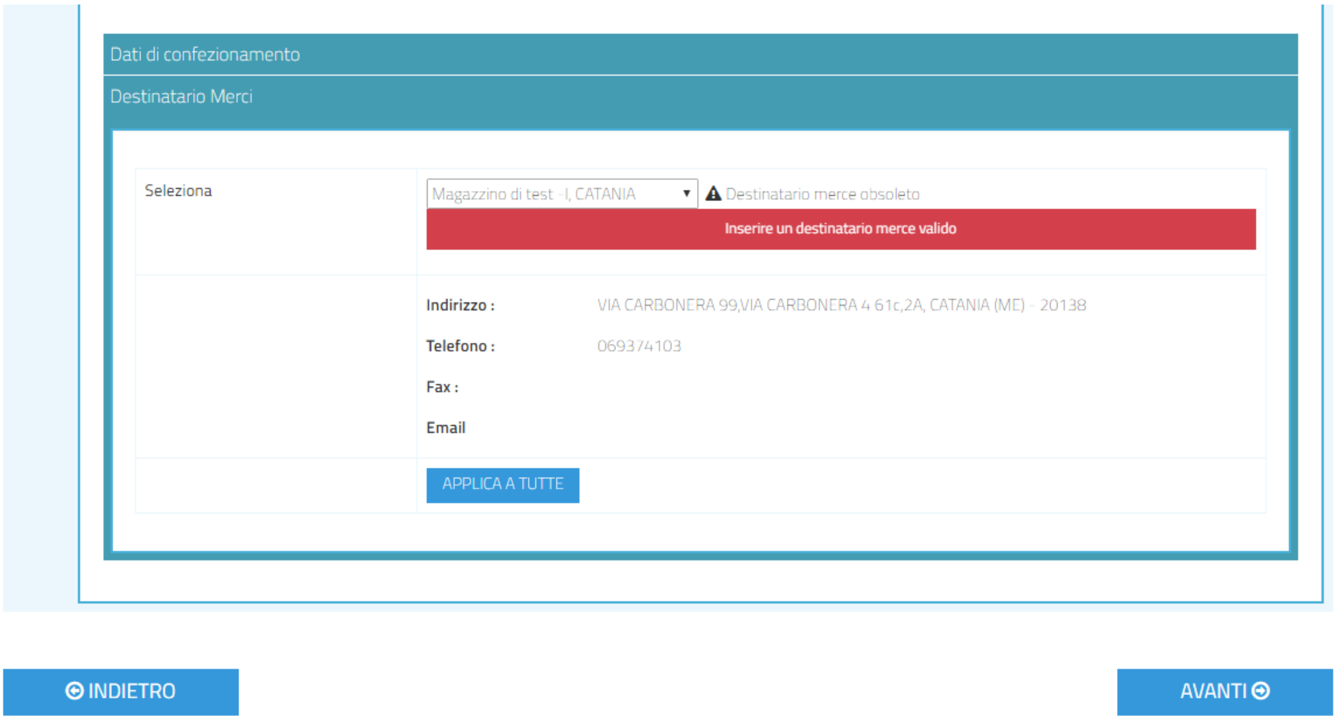
The system will provide the transaction message:



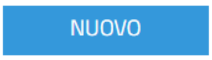
Warning: if you "DISABLE" a Goods Consignee this will be no longer visible between the delivery points selectable under Order Processing (Step 3).

11.3.2 Orders containing obsolete consignee

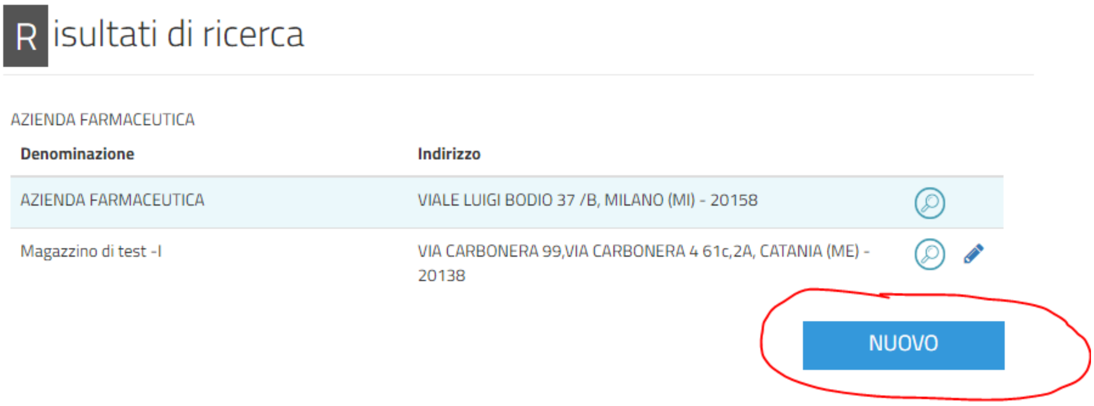
When the user changes or disable a Consignee, the Drafts/ Templates previously created still contain the "old" Consignee. If the user tries to confirm those Drafts/templates, the system returns an error message, in the section on step 3, inviting the user to choose a valid consignee.



11.4 Add a new consignee

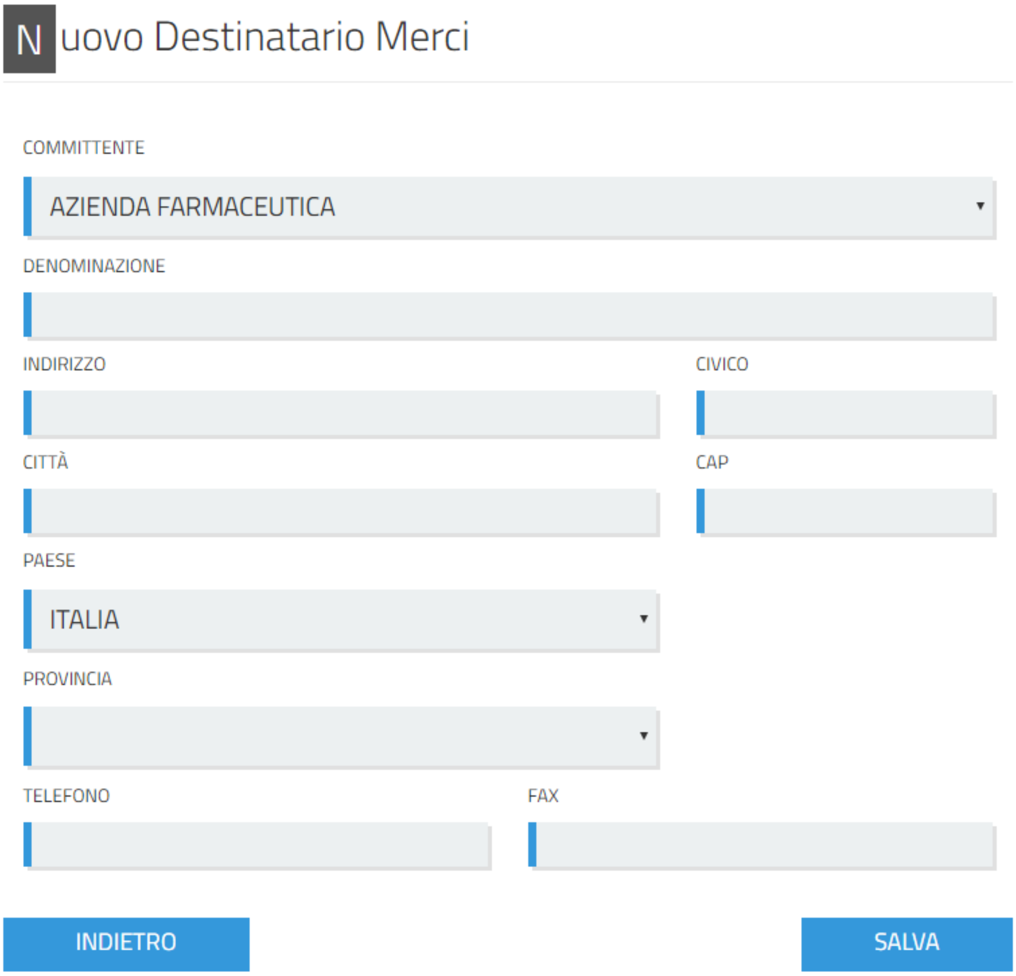
By clicking on the icon 

you can enter a new Goods Consignee:

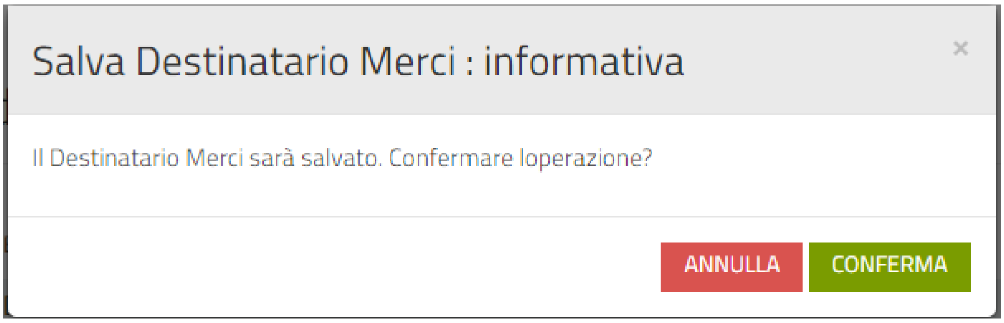


In "New Goods Consignee" page, the user can valorize the following data:

- customer. If the user is associated with several pharmaceutical companies, you need to choose which company you want to join with the new Consignee. (Required)
- denomination. Is the definition of consignee. (Required)
- address. (Required)
- Street number
- City. (Required)
- Postal code (required)
- country. (Required)
- province
- telephone
- Fax



To save data click on "SAVE" button and then confirm or cancel the operation:



If the user presses the "Confirm" button , the system returns the message of the successful operation.

The new Goods Consignee will be visible between the delivery points selectable under Order Processing (Step 3)

12 USERS MANAGEMENT

Users management features allow you to determine how users operate within the portal. With the functions described below it will possible to make an accurate users' profiling associated with the companies.

12.1 Search Users

The search feature allows users to view the list of users associated with a company. This feature is available to users enabled to the user management role (read-only).

To perform an users search, click the menu item users and subsequently the subheading SEARCH USERS.

The portal will show the form of users search. It is possible to search filtering the following fields:

- Last name
- Tax code

The tax code must correspond to a valid tax code.

By pressing the SEARCH button, the portal will display the list of users with the Following information:

- Name (last name in caps, and name);
- Tax code;
- date of last change.

Risultati di ricerca

Nominativo	Codice Fiscale	Username	
ROSSI Alessio	LSSRSS00D01H501F	XXXXXXXXXXXXXXXX	
ROSSI Antonio	RSSNTN00R01H501D	XXXXXXXXXXXXXXXX	
ROSSI Michele	MCHRSS00D01H501I	XXXXXXXXXXXXXXXX	

3 elementi trovati, mostrati tutti gli elementi.

Please note that displayed users works for the same company of the user doing the operation.

Depending on authorizations granted, the logged user is allowed to perform this two operation:

• read-only view of a user's information in case it has just read-only users management role; in this case, it will have a single icon that displays the link functionality;

Nominativo	Codice Fiscale	Username	
ROSSI Alessio	LSSRSS00D01H501F	XXXXXXXXXXXXXXXX	

• to change a user's information (functions described in section 12.3), proceed to its activation / deactivation and assign roles if it has users management role (creating/editing); in this case it will have the corresponding icons to links to user editing features and user roles;

Nominativo	Codice Fiscale	Username	
ROSSI Alessio	LSSRSS00D01H501F	XXXXXXXXXXXXXXXX	

12.2 New Users

An user enabled to users management role in creating / editing has the ability to insert other users within the company for which he works. Is possible to add new users not yet registered to the portal or add existing users and enable them to act on behalf of other companies.

Please note that within the portal a user is uniquely identified by its tax code.

To create a new user, select the menu item USERS and subsequently the subheading NEW users:

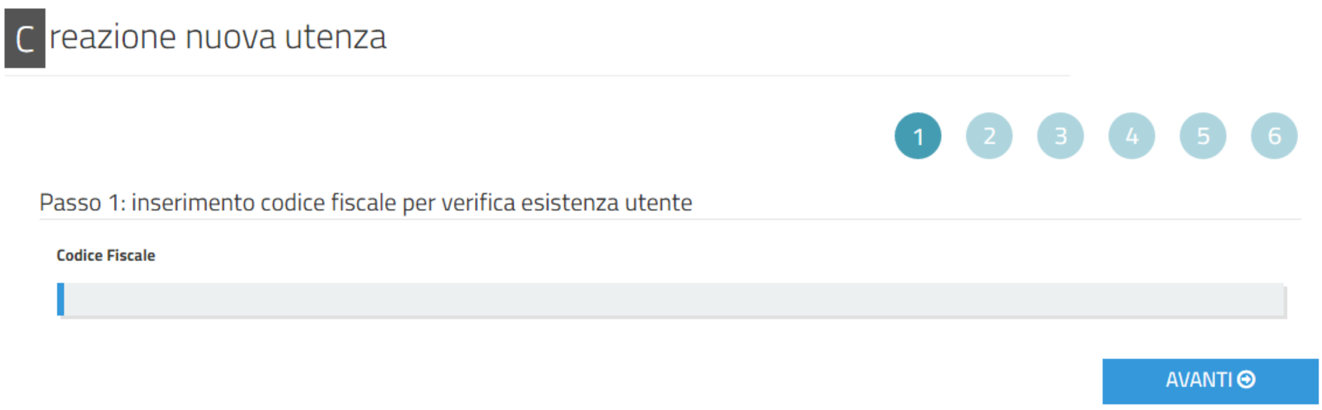
The portal will present the mask of the new user wizard. It will then proceed with a series of sequential steps to enter all the information you need for create and/or register a user of a company.

At every step you can check all the data entered.

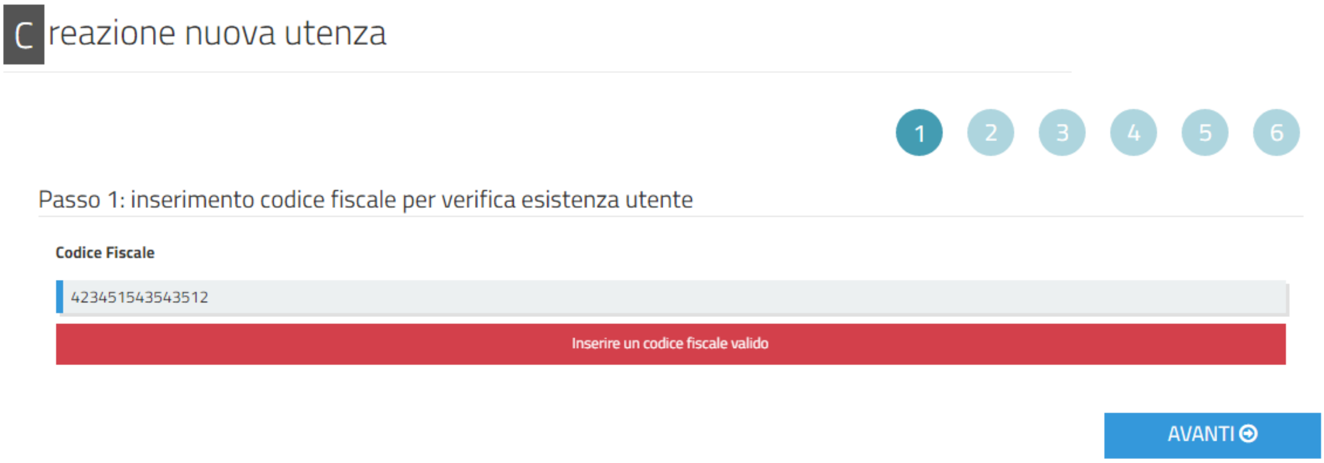
12.2.2 Creating user step 1: input tax code

E' necessario essere a conoscenza del codice fiscale dell'utente che si vuole registrare, inserendolo nella casella di testo a disposizione e proseguendo cliccando sul tasto AVANTI:

It is necessary to aware the tax code of the user who you want to record, inserting it in the text box and click on NEXT:



The Portal makes the verification of the validity of the tax code, and will block the progress of the procedure if the tax code is not valid.

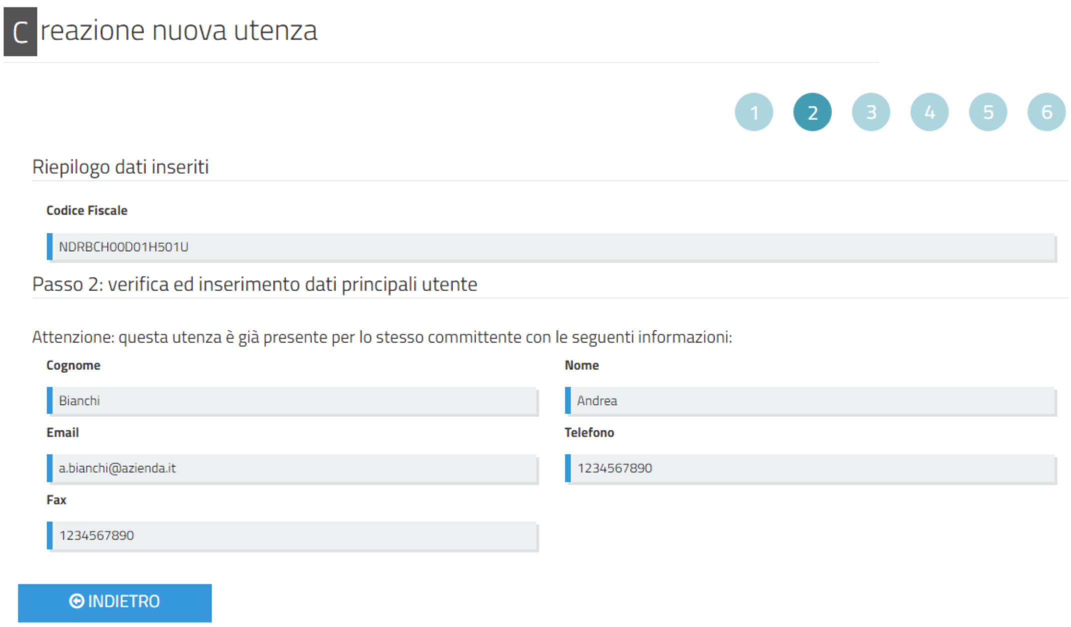


When properly inserted, the procedure continues to step 2

12.2.3 Creating users step 2: insert main user data

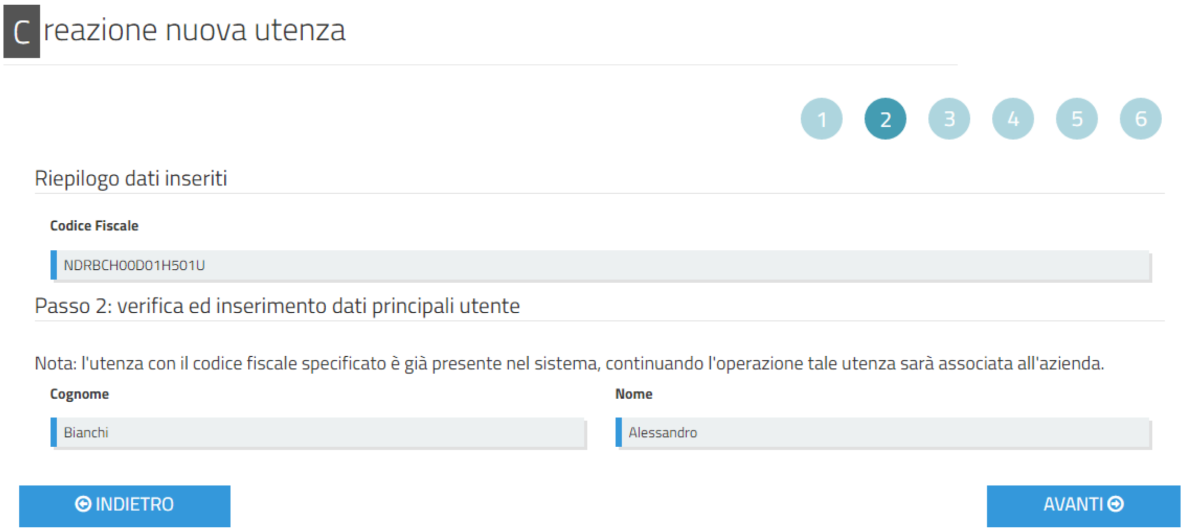
Once the portal has carried out the verification of the tax code entered, it may occur the cases described below. In all cases it is possible to return to previous step by clicking the BACK button.

- **Caso 1**: The user is already on the Portal and associated with the company for which you are working:



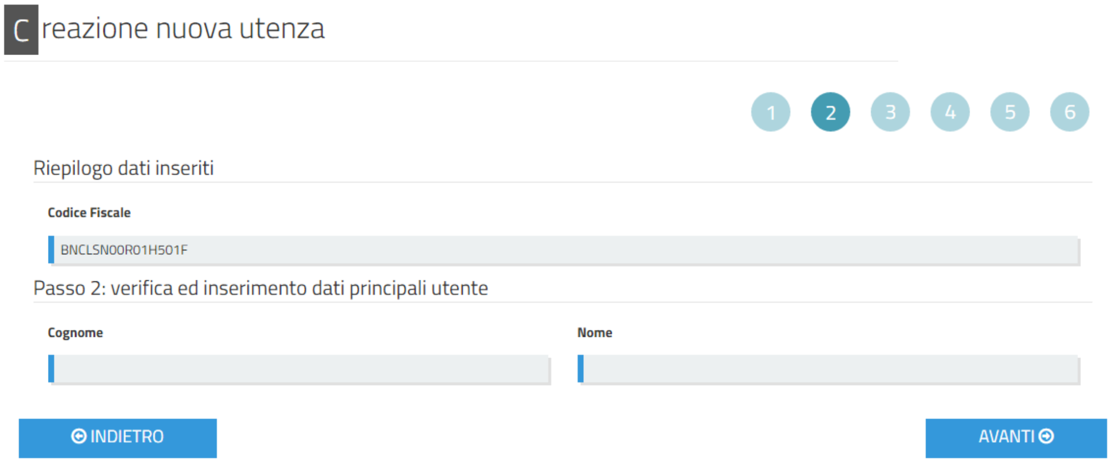
In this case is not possible to continue with the procedure because the user is already registered with the company, but you can work to the associated user accessing to User editing features, enabling/disabling and User Roles (described in paragraphs 12.3, 12.4 and 12.5);

- • **Case 2:** the user is already on the portal, but it is not associated with the company for which you are working:



Being the user already present on the portal, you don't need to enter personal details (name and surname). By clicking to NEXT button you can proceed to step 3;

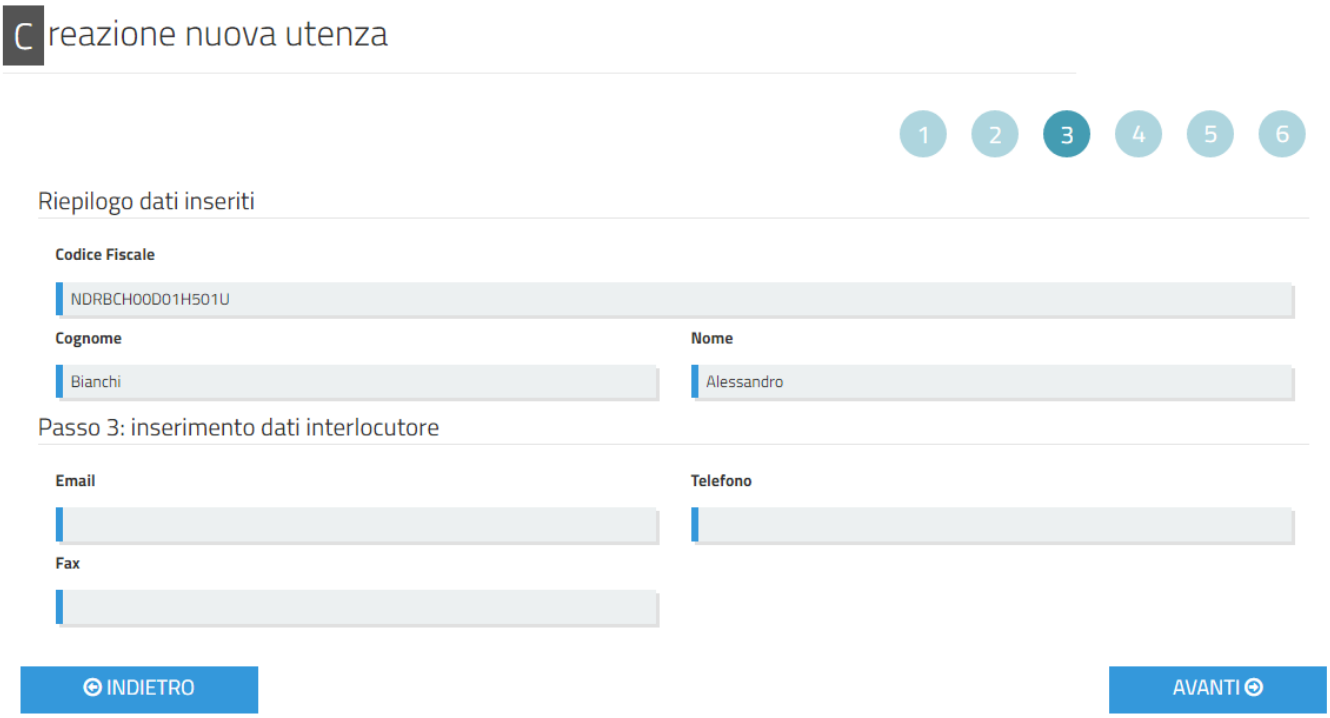
- **Case 3**: the user is not present on the Portal:



Enter First and Last Name in the appropriate text boxes for user who want to create (both fields are required). Clicking the Next button will bring you to step 3.

12.2.4 Creating users step 3: enter personal details

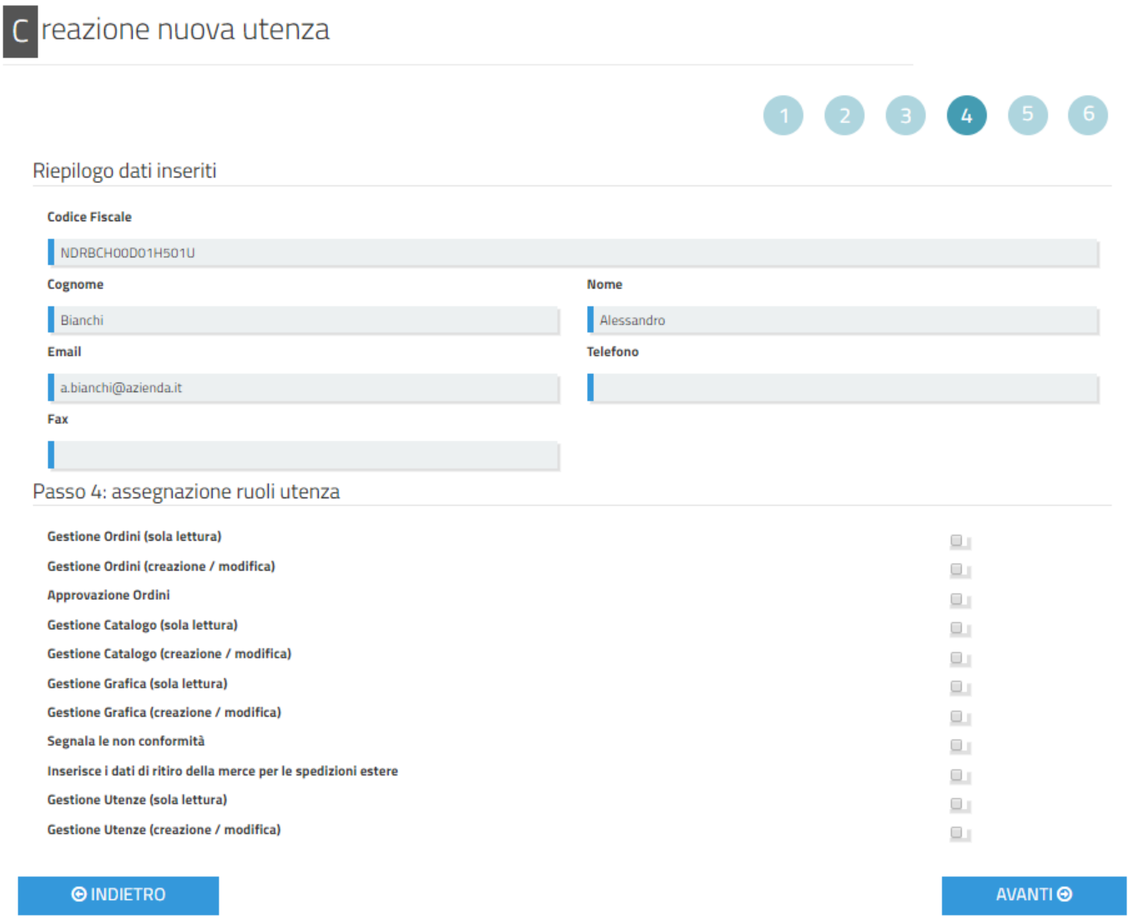
Enter the reference data for new user about the company you want to bind to (Email, telephone and Fax). The Email field is required as used as the address for communications from the portal to user concerning the company:



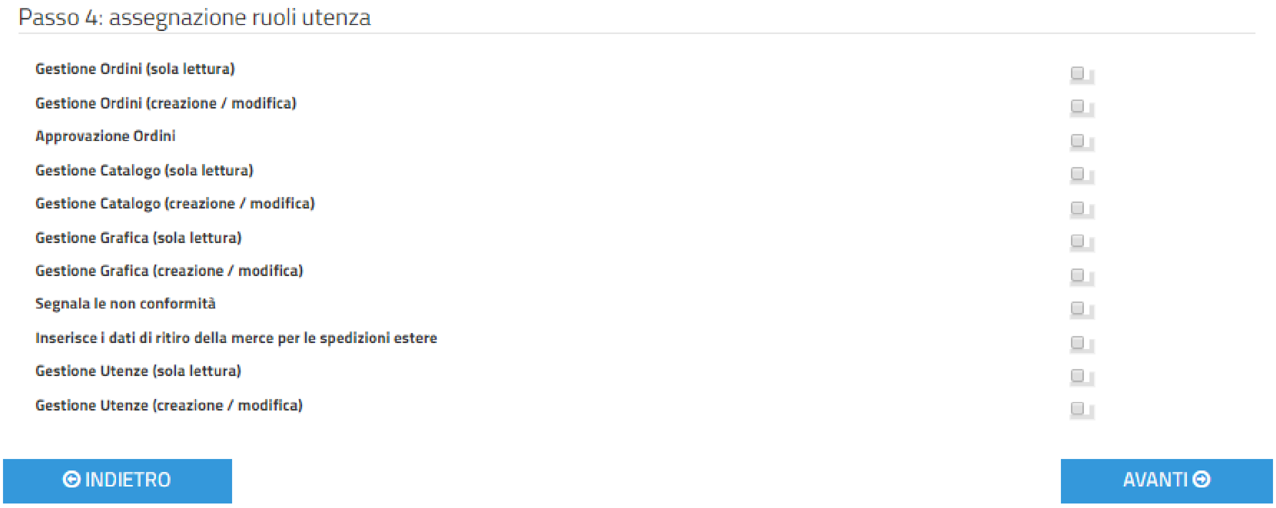
After entering the information, you can proceed to step 4 by clicking the NEXT button, or return to previous step by clicking on BACK button.

12.2.5 Creating users Step 4: assign user roles

Once entered reference data and corporate contact, associate the roles to users by selecting them from among those available:



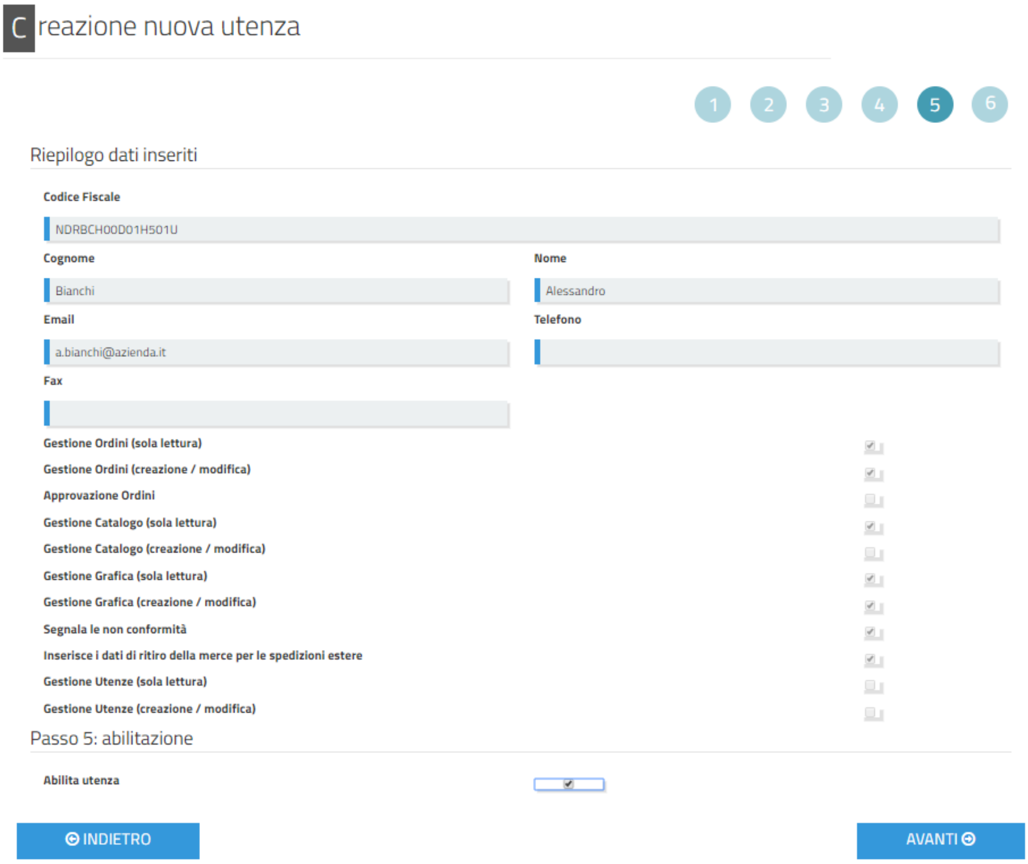
In case you select a role that inherits other roles, the latter will be automatically selected, it will be not clear until the role "child" is not cleared (Note: this feature is only available if your browser support Javascript, otherwise the roles will not be selected until the end of the wizard).



Once you have selected the roles to be assigned, you can proceed to step 5 by clicking on the next button, or return to the previous step by clicking on BACK button.

12.2.6 Creating users Step 5: enable

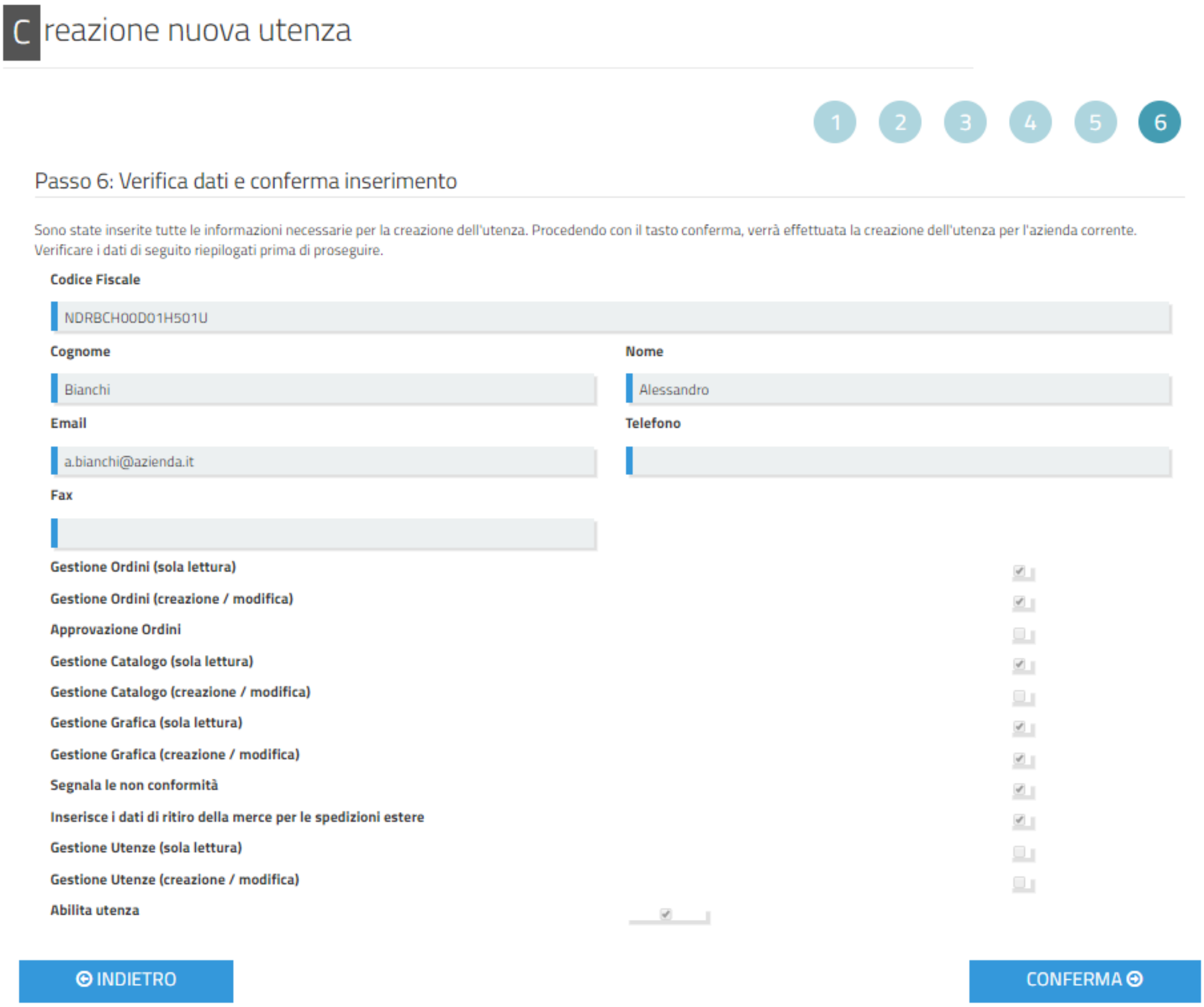
Choose whether to activare or not the user at the moment of creation by selecting the option Enable Users:



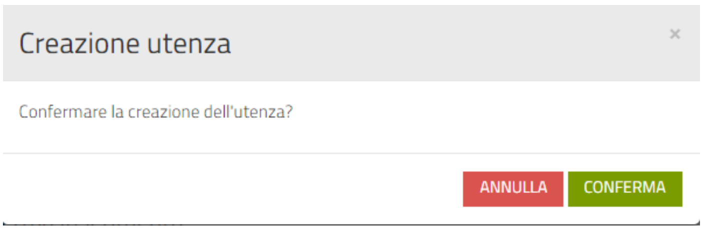
Then proceed to step 6 by clicking the NEXT button, or go back to the previous step by clicking the BACK button.

12.2.7 Creating user step 6: checks and confirm data

In this step all information is summarized. Click on the CONFIRM button to go ahead with the procedure, or click BACK button to return to the previous step.



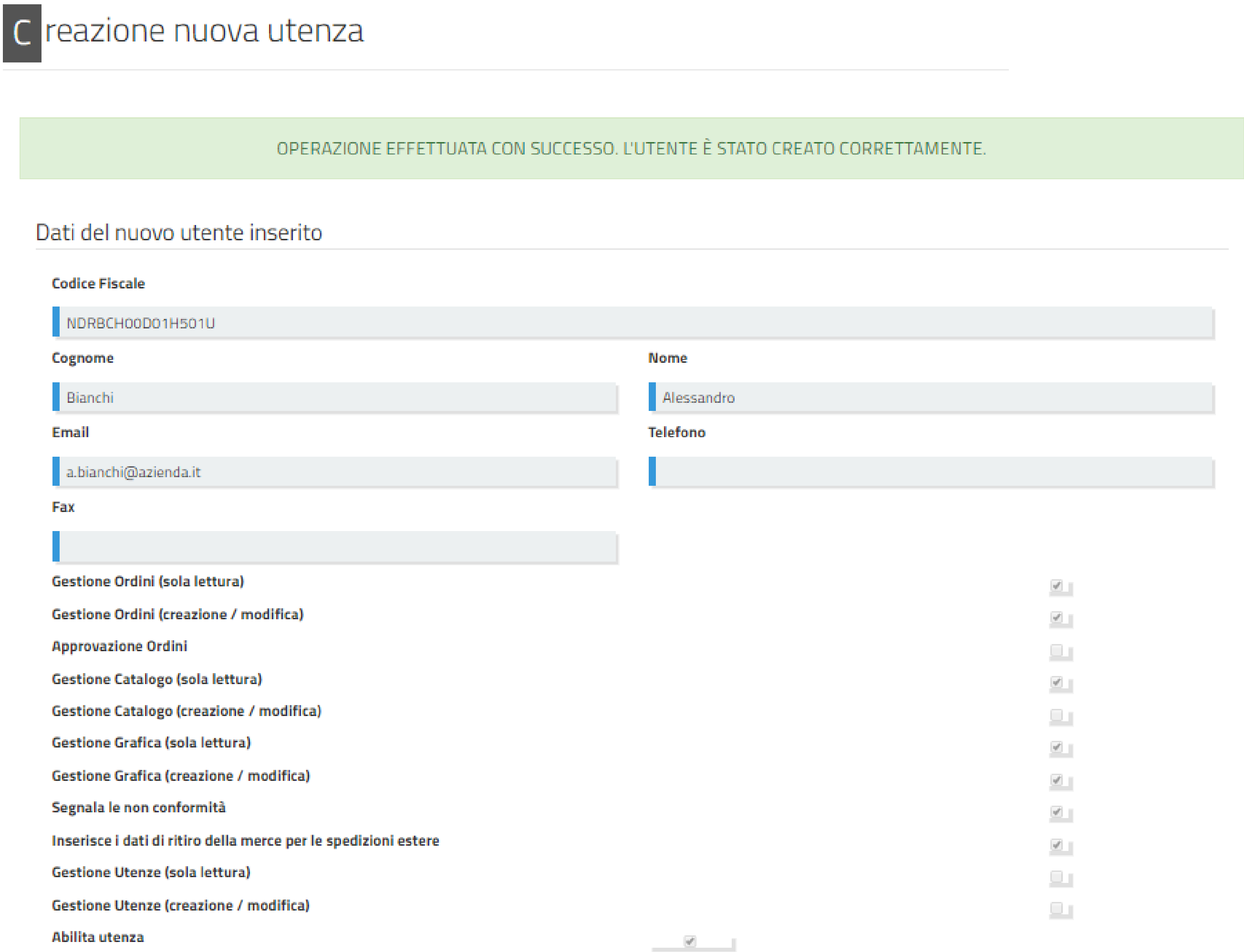
Before proceeding with the creation of the users the portal will present a further confirmation request:



Click on the CONFIRM button to complete the procedure and actualize the creation of users. Click on the CANCEL button to return to the summary screen.

12.2.8 Confirms creation and sending notifications

Once the creation of the user is completed, the portal will display a message about successful operation:

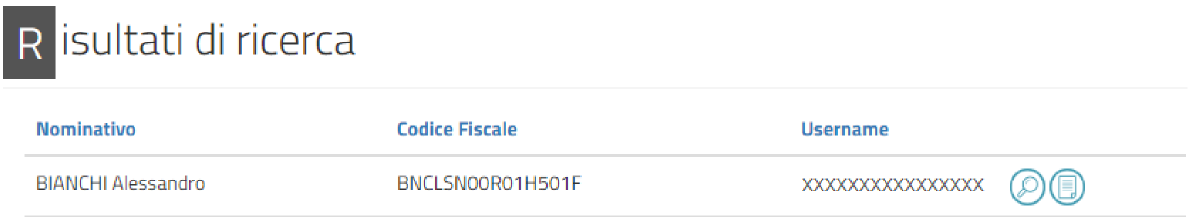


As a result of saving the Portal will automatically sends notifications to the address specified in the e-mail field:

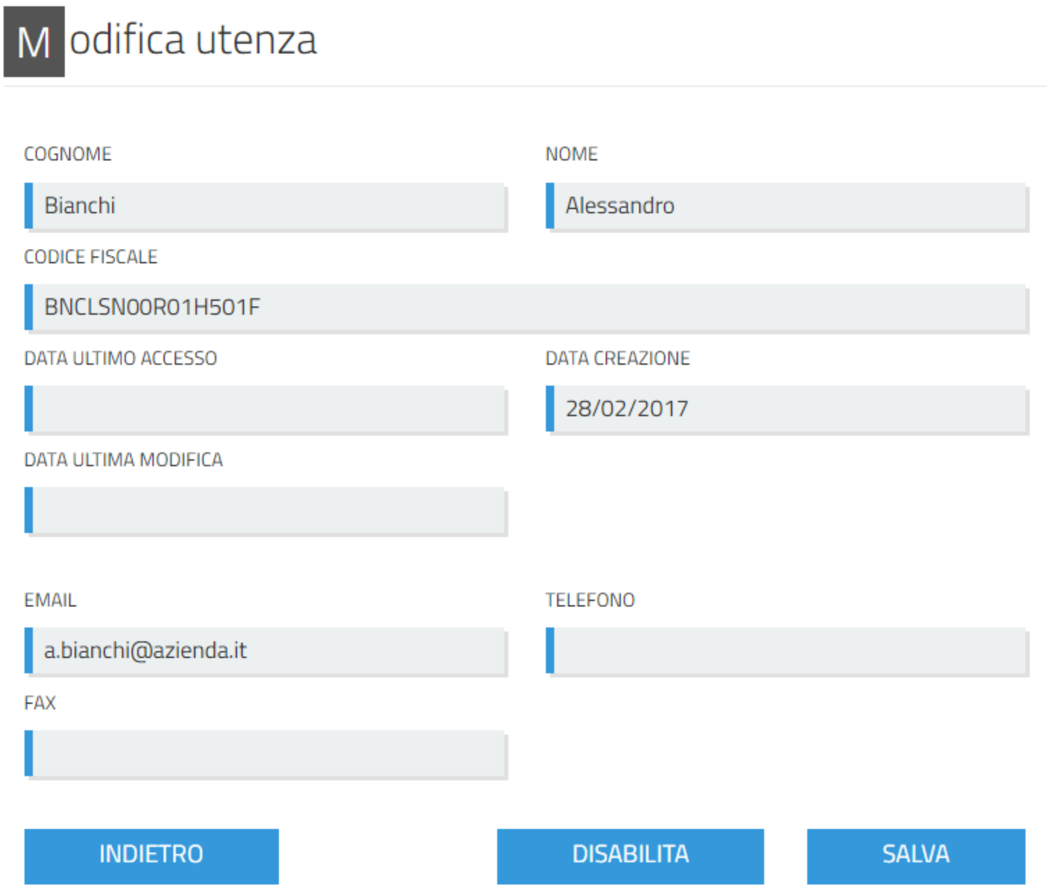
- • If the user was not present on the portal while creating, it will sent two notifications:
  - A summary notification of the user's business data and authorizations granted;
  - A notification including first login credentials;
- In case the user is already present on the Portal at the time of creation, just a single notification will be sent to the user's enterprise, summary data and authorizations granted

12.3 Edit User

An user enabled to <u>users management role (create/edit)</u> has the ability to edit information of user.
From the user list in search section, select the magnifying glass icon to access to edit user form:

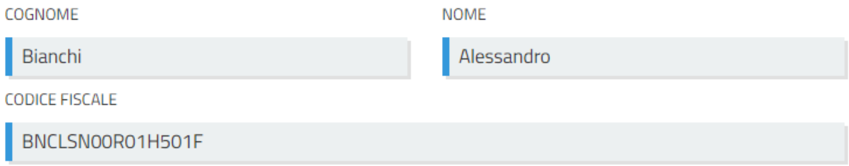


The portal will display the edit user form:

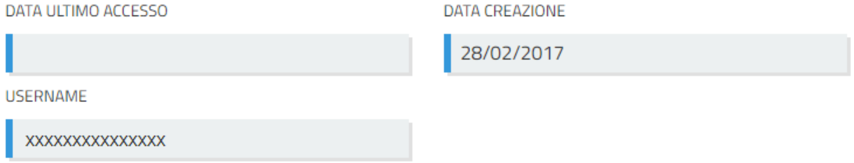


The module is divided into three groups of information that can be changed according to user status:

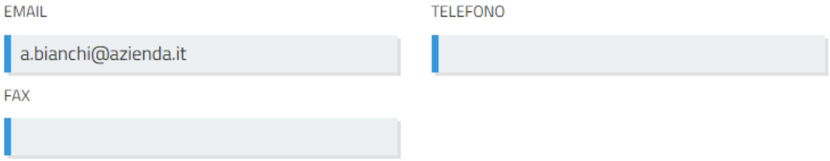
- *Name, first name, tax code*: are personal data of the user. You can edit them only in case the user is disabled and it has not accessed to the portal;



- *Last access date, creation date, last modified date:* Those are information relating to personal data and are always available as read-only*;*



- *E-mail, phone, fax:* are user data such as company contact. It is always possible to modify them, and the email field is required (user's notifications are sent to the address specified in this field);



By clicking on the SAVE button the Portal performs saving of these new information; by clicking on BACK button will return to the previous screen (search users). The Portal shows a confirmation message of occurred change and will send an email summarizing user's business data and authorizations granted.

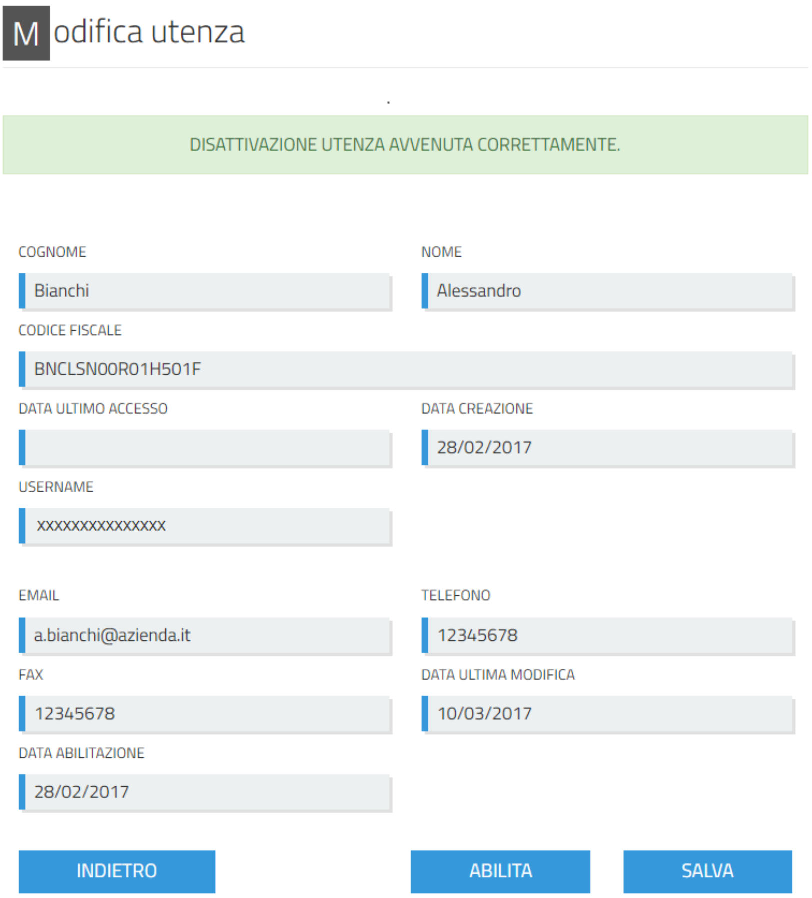
12.4 Enable/disable users

From Edit User form you can enable/disable company's users. Disabling involves the denial for a user to operate; therefore disabled user cannot access the functionality for that company.

12.4.1 Disabling

If the user is enabled you can disable it by pressing the DISABLE button:

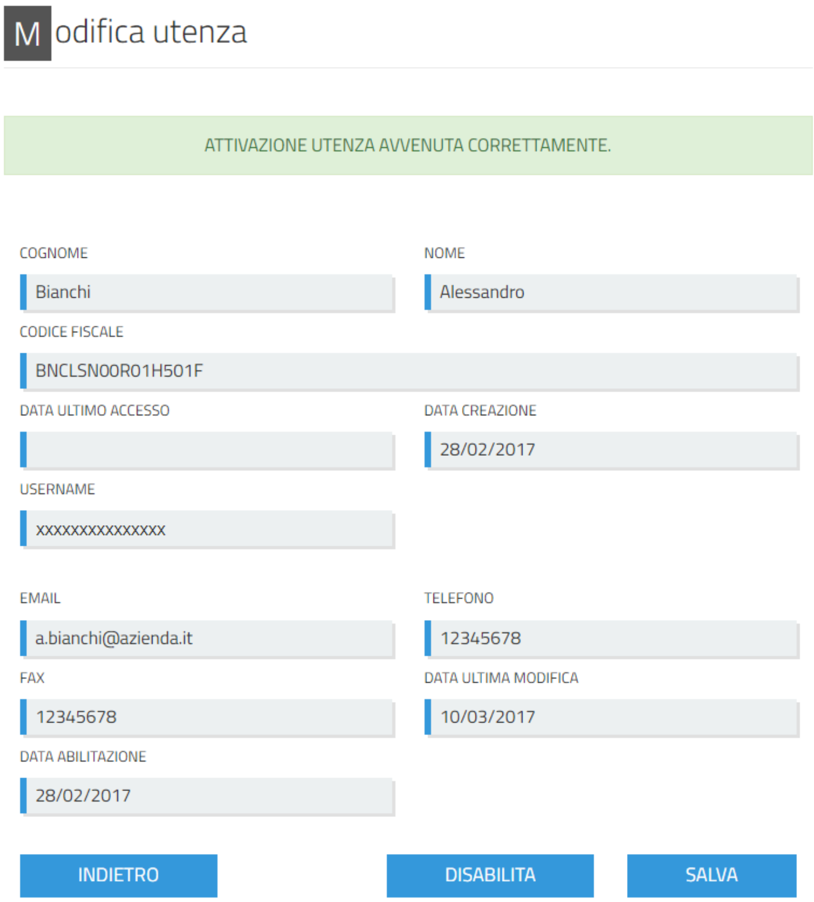
As a result of disabling the portal will display a confirmation message and will notify information to the specified address in the email field:



12.4.2 Enabling

If the user is disabled you can enable it by pressing the ENABLE button:

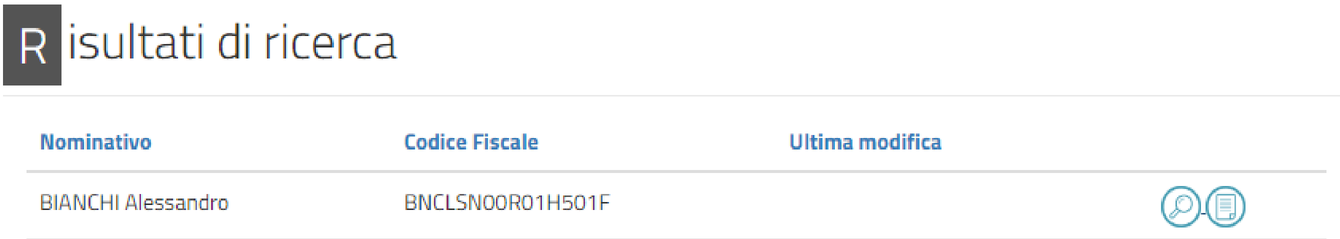
As a result of enabling the portal will display a confirmation message and will notify information to the specified address in the email field:



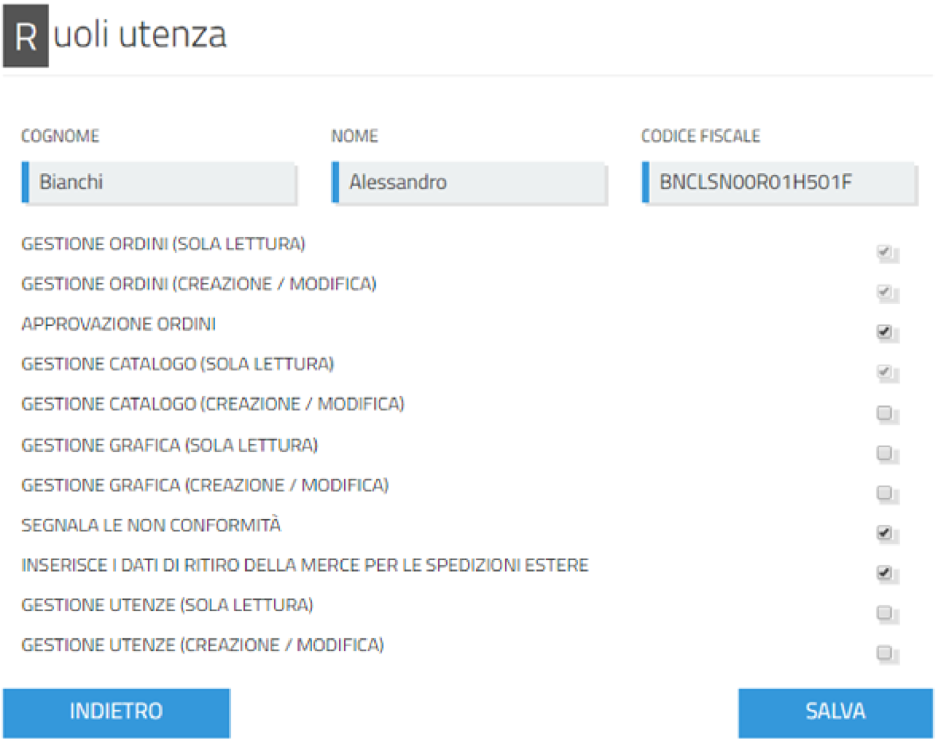
12.5 User Roles

An user enabled to users management role in creation / modification has the ability to assign / remove application roles to an user on behalf of the company for which he works.

From the user list in search section, click the document icon to access the user roles module:

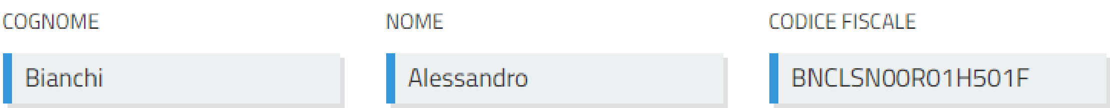


The portal will display the Following form to assign roles:



The module is divided into two groups of information:

- *name, first name, tax code:* user's personal information, read-only;



- *Application Roles* -- is the list of roles for which you can enable a user. For each role are associated specific features of the portal. Enabling a role will lead for the user the access to the associated features:

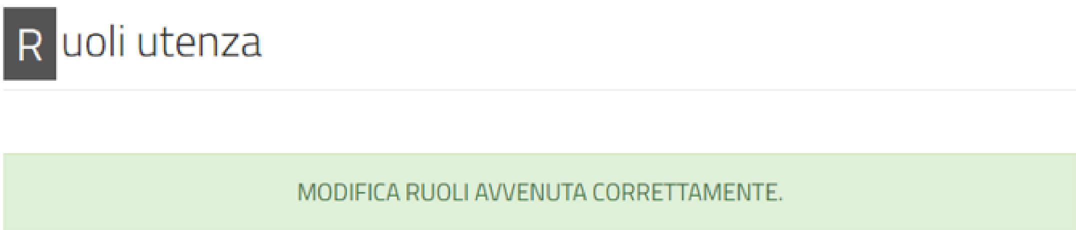
GESTIONE ORDINI (SOLA LETTURA)	☑
GESTIONE ORDINI (CREAZIONE / MODIFICA)	☑
APPROVAZIONE ORDINI	☑
GESTIONE CATALOGO (SOLA LETTURA)	☑
GESTIONE CATALOGO (CREAZIONE / MODIFICA)	☐
GESTIONE GRAFICA (SOLA LETTURA)	☐
GESTIONE GRAFICA (CREAZIONE / MODIFICA)	☐
SEGNALA LE NON CONFORMITÀ	☑
INSERISCE I DATI DI RITIRO DELLA MERCE PER LE SPEDIZIONI ESTERE	☑
GESTIONE UTENZE (SOLA LETTURA)	☐
GESTIONE UTENZE (CREAZIONE / MODIFICA)	☐

To assign a user role, click on the checkbox next to the role. The inheritance role management follows the same rules as in Step 4 of the User Creation (see section 12.2.4).

Note: If you are making change of roles for the user who is operating (which can be viewed as a modification of "themselves"), the Portal prevents the inhibition of roles USERS MANAGEMENT (READ ONLY) and USERS MANAGEMENT (CREATION / MODIFICATION)

Click Save button to save the assignments made. Click on the back button to return to the previous screen (search users).

After saving the portal will show a message of successful user roles assignment and will send a notification to user's email address a notify a summary of business data and authorizations granted (see Edit user):



12.6 SuperUser promotion

An user enabled to "SuperUser Promotion" role, has the ability to assign the SuperUser's profile to users associated with the company for which he works.

To access this feature, select the menu item USER and subsequently the subheading SUPERUSER PROMOTION

The portal will display Users search mask similar to that one of section "Research Users" (see section 12.1). It is possible to search by filtering the following fields:

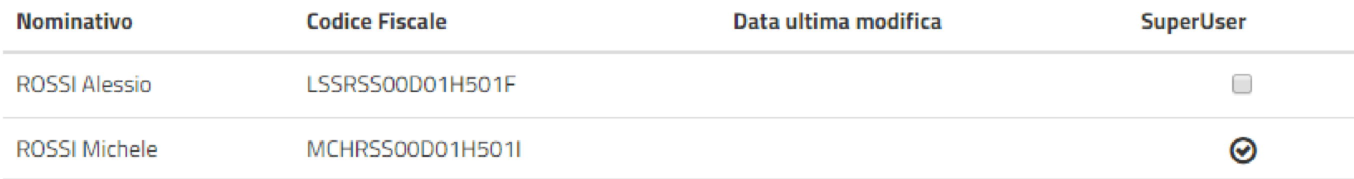
- Last name
- Tax code

The tax code must correspond to a valid tax code.

By pressing the search button, the portal will display the list of users with the Following information:

• Name (last name in caps, and name);
• Tax code;
• last modified date
• SuperUser status;

The portal distinguishes users with that profile than those who do not with a circle popped up on SuperUser column.



Note: in search results is excluded the user who is currently operating.

To select one or more users to promote select the checkboxes for each user:

ROSSI Alessio	LSSRSS00D01H501F	☑

Once selected, click on Promote button to proceed to save. Before proceed the portal will present an additional confirmation request:

Promuovi SuperUser ×

Attenzione: gli utenti selezionati verranno promossi a SuperUser.
Questo profilo eredita tutte le funzionalità previste dal portale, confermare?

ANNULLA PROMUOVI

Click on PROMOTE button to complete process and promote selected users to SuperUser. Click on Cancel button to return to previous screen.

After saving the portal will show a message of successfull assigned operation and it will send to the email address of each user selected a summary notification of promotion to SuperUser profile including summary of all authorizations granted. All users selected before saving will now no longer selectable:

PROMOZIONE A SUPERUSER AVVENUTA CORRETTAMENTE.

Risultati di ricerca per promozione SuperUser

Nominativo	Codice Fiscale	Data ultima modifica	SuperUser
ROSSI Alessio	LSSRSS00D01H501F		✓
ROSSI Michele	MCHRSS00D01H501I		✓
ROSSI Antonio	RSSNTN00R01H501D		☐

3 elementi trovati, mostrati tutti gli elementi.

13 MANAGEMENT OF NON-COMPLIANCE REPORTS

Through the functionalities described in this chapter will be possible to forward non-compliance reports that could be found by customer for a specific production lot.

The target is to realise a communication channel between user of Portale Unico Valori and the Istituto Poligrafico e Zecca dello Stato to permit a lean and speed management of non-compliance reports.

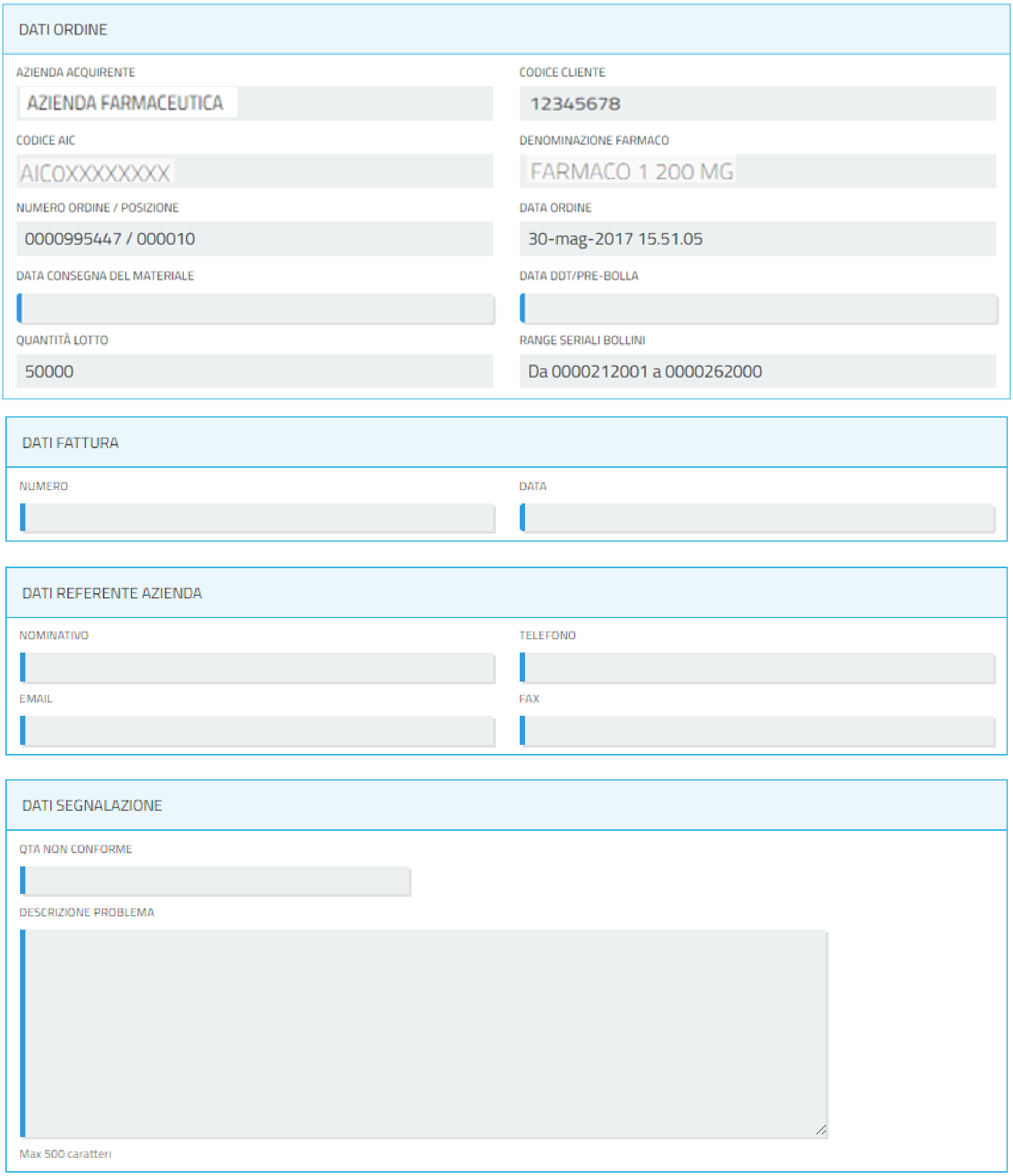
For each position of an order will may be forwarded one or more reports of non-compliance. The reports will may be sent only if the position of order will got the state “Invoiced”.

13.1 Create a report

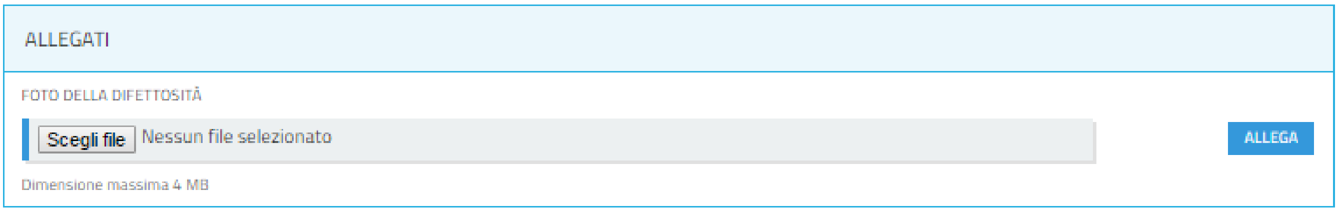
To enter on the page “Order Detail”.

If the selected postion have got the state “invoiced” will be present a button “NEW REPORT” (see you highlighted button in the below picture).

Pressing the button “NEW REPORT” will open a page to insert datas of the non-compliance report:



DATI ORDINE
AZIENDA ACQUIRENTE
AZIENDA FARMACEUTICA
CODICE CLIENTE
12345678
CODICE AIC
AICOXXXXXXXX
DENOMINAZIONE FARMACO
FARMACO 1 200 MG
NUMERO ORDINE / POSIZIONE
0000995447 / 000010
DATA ORDINE
30-mag-2017 15.51.05
DATA CONSEGNA DEL MATERIALE
DATA DDT/PRE-BOLLA
QUANTITÀ LOTTO
50000
RANGE SERIALI BOLLINI
Da 0000212001 a 0000262000
DATI FATTURA
NUMERO
DATA
DATI REFERENTE AZIENDA
NOMINATIVO
TELEFONO
EMAIL
FAX
DATI SEGNALAZIONE
QTA NON CONFORME
DESCRIZIONE PROBLEMA
Max 500 caratteri



In the section “DATI ORDINE” will be viewed the following informations:

DATA PRE COMPILED FROM SYSTEM:

- **Buyer Company**: it’s the pharma company that has bought the production lot.
- **Customer Code**: it’s the identification code of the pharma company has bought the production lot.
- **AIC Code**: it’s the identification code of drug for wich the non-compliance report will be sent.
- **Drug Name**: it’s the name of the drug.
- **Order Number / Position**: it’s the number of position in the Order for wich the non-compliance report wll be sent.
- **Order Date**: it’s the go forward date of the Order to IPZS.
- **Lot Quantity**: it’s the quantità of the production lot.
- **Serial Range of Bollini**: it’s the numbering range of the production lot.

DATA TO INSERT (required)

- **Delivery Date of the Ware**: Date when the customer has received the lot.
- **Data DDT / PRE-BILL**: it’s the date on the delivery note (DDT) used if the ware is sending in Italy, or it’s the date on pre-bill document (if the ware is sending abroad)

In the section “INVOICED DATA” will be compiled the follow info:

- **Number**: it’s the invoiced number for the production lot.
- **Date**: it’s the date of the invoiced emitted. (required)

In the section “DATA OF REFERENT COMPANY” will be compiled the follow info:

- **Name**: it’s the name of user sends the non-compliance report (required).
- **Phone**: phone to communicate info to the user (reuired).
- **Email**: email to communicate info to user (required).
- **FAX**: fax number to communicate info to user.

In the section “REPORT DATA” will be compiled the follow info:

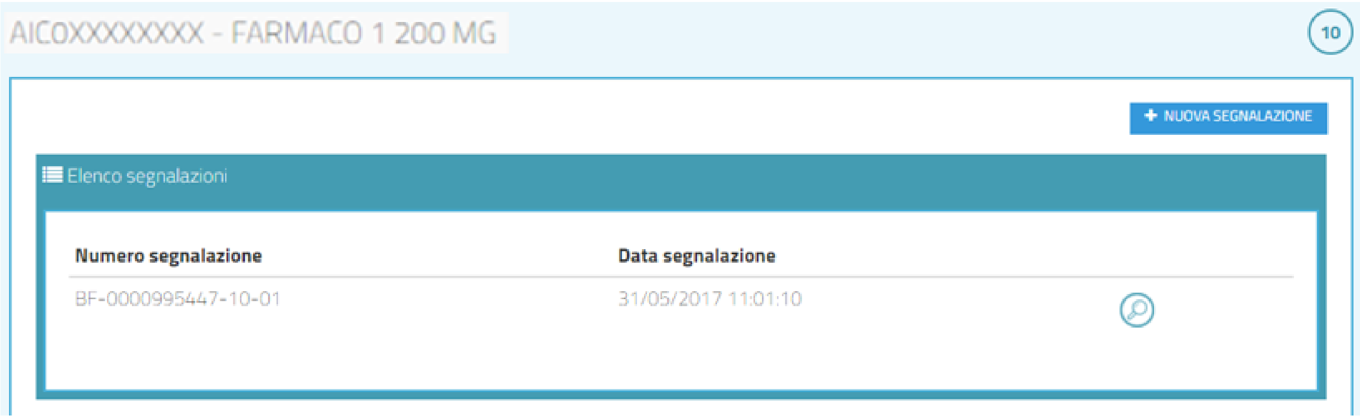
- **QTA non-compliance**: it’s the quantity of the production lot will resulted non-compiance of the lot. The value can’t be more than the total quantity of the lot (required).
- **Problem Description**: the description of the problem found. Max 500 chars available.

In the section “ATTACHMENTS” will be attached the follow info:

The user will shall attach some picture to showing the found problems. Each picture will must be max 4 MB.

13.2 View non-compliance report

Each report will be showed inside the order detail like the follow picture:



The non-compliance report will be named with the follow data splitted from “-” character:

- BF
- Number of the Selling Order
- Position
- Progressive Counter

The button “magnifying glass” opens the report detail.