



Agenzia Italiana del Farmaco

AIFA

Rinnovi (Renewal)
User Manual

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1 Introduction

This document is intended to be a user manual explaining the functions of the Rinnovi (Renewal) System.

This guide aims to describe the procedure to be used for the evaluation of renewal requests of drugs' marketing authorization (MA) nationally authorized and mutual recognition.

In order to submit a renewal request to the Medicines Agency using Rinnovi system, the company has to :

- Fill in the electronic Application Form (in PDF format)
- Attach the PDF document previously generated and its XML file (generated by the PDF Application Form itself).
- Select the AIC code (Medicinal Product marketing authorization number) .
- Attach all the documentation related to the application in electronic format.
- Insert, as far as the factory is concerning , the relative packages, the reported phase is done for and the possible notes.
- Insert, as far as the factory is concerning, the active substances, the API name and possible production phases
- Send the originally signed Application Form together with the supporting documentation in paper version to the Italian Medicines Agency.

During the assessment of the application and/or upon formal request by AIFA the applicant is allowed to submit further documents in response to the request of information.

The pharmaceutical company should also, in agreeing with the process already in place:

Send in a paper form of all the documents concerning its request with CD/DVD for the technical documents. attached to it.

Together with the paper form documents , the company should include the frontispiece (the printed receipt issued by "Rinnovi" system).

2 System Description

2.1 Notes

In order to use the system functions at the best you have to follow the f indications given below.

2.1.1 Selection of the Web Browser

To be able to use the system , you should use one of the following web browsers

For Linux Operating System :

- FireFox 3.6 or Firefox 7.0
- Google Chrome 14

For Mac Operating System :

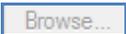
- Safari 5.1

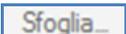
For Microsoft Windows Operating System :

- FireFox 3.6 or Firefox 7.0
- Google Chrome 14
- Internet Explorer 8.0

The personal settings of the web browser could determine differences on how some visual elements appear; you will find below an example of how the function “Scegli file” may appear:

 Button 1

 Button 2

 Button 3

Other web browsers are not fully supported.

2.1.2 Navigation Mode

The interaction model between the user and the system is the typical one in the Internet environment, where the above cited interaction is made through visual elements in textual and iconographic mode to facilitate the user actions.

For a correct navigation, the address at the top of the screen (URL - Uniform Resource Locator) has neither to be used within the browser nor direct reference pages commands (for example: Forward, Back, Refresh, Favorites , History, etc..), while), or the commands made available by the application.

3 Functionality Description

3.1 System Access

NOTE: as pre-requisite for access to the system :

- The pharmaceutical companies should have their SIS code and have completed the pre-registration procedure on the Italian Medicines Agency authentication system.

to access the system , please select the following link [Portale Rinnovi](#) , that can be reached from the following address <http://www.agenziafarmaco.gov.it/frontend/> and enter your access credentials (username and password)



The image shows a screenshot of the AIFA Rinnovi login page. At the top center, there is the AIFA logo, which consists of a circular emblem with a star and the text 'Agenzia Italiana del Farmaco' and 'AIFA'. Below the logo, the word 'Rinnovi' is displayed in a large, bold, black font. Underneath, there is a light gray rectangular box containing the login form. The form has two input fields: 'Inserisci username:' and 'Inserisci password:'. Below the password field, there is a button labeled 'accedi'.

Figura 1: Login page

If the user is associated to more companies (codes SIS), you have to choose the structure you want to work for, by selecting the related option among the available ones in the drop-down menu, that is shown in the following picture.



The screenshot shows the AIFA logo and 'Rinnovi' header. Below is a form titled 'Selezionare il codice SIS'. It contains the following fields: 'User Id' with the value 'RAIC.Esterno', 'Codice SIS' with a dropdown menu showing '2336', and 'Descrizione SIS' with a text box containing 'NUOVA ATMA PHYSIS S.R.L.'. A 'Conferma' button is at the bottom left, and an 'Esci' button is at the top right.

Picture 2: Selection of SIS code

After having selected the SIS code and clicked the button “Conferma”, you will be redirected to the home page as in the following picture.



The screenshot shows the AIFA logo and 'Rinnovi' header. Below is a search form titled 'Criteri di Ricerca'. It contains the following fields: 'User Id' (RAIC.Esterno), 'Codice Pratica', 'Codice AIC', 'Data Protocollo', 'Inizio', 'Fine', 'Numero Protocollo', and 'Stato Pratica'. There are 'Ricerca' and 'Annulla' buttons at the bottom left, and an 'Esci' button at the top right.

Picture 3: home page

The ‘User id’ field displays the username of the logged user.

The other fields are the “Search criteria” available to the user to view his own files using the button “Ricerca”.

The description of the system functions that can be used by the user are indicated below:

- Create a new file
- Search file
- Edit file

3.2 Create a new dossier

The function “Nuova Pratica” allows the Applicant to submit a renewal request .

Before starting to make the submission of the application, the electronic application form (PDF) should have been previously downloaded by the EMA website (<http://esubmission.emea.europa.eu/eaf/>) and filled in with all requested information:



After the completion of the Application Form, it is mandatory to make the following utilities run :

- Validate Form: Checks the entered data and it validates its consistency
- Save Form: saves the electronic form in PDF format
- Export XML: creates a new XML file contains the inserted data in the Application Form.

Then, you will be able to proceed with the insertion of a new dossier on "renewal" through the following screen.

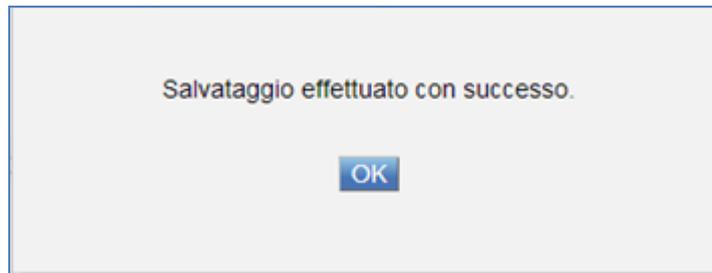
The screenshot shows the 'Rinnovi' (Renewals) section of the AIFA website. The header includes the AIFA logo and the text 'Agenzia Italiana del Farmaco' and 'Rinnovi'. The main form area contains several sections: 'User Id' with a text box containing 'RAIC Esterno'; 'Codice Pratica' and 'Numero Protocollo' with empty text boxes; 'Codice SIS' with a dropdown menu showing '8043' and 'Descrizione SIS' with a dropdown menu showing 'ZENTIVA ITALIA S.R.L.'; 'Acquisizione Application Form' with 'File PDF' and 'File XML' text boxes and 'Browse...' buttons; 'Acquisizione Codice AIC' with a 'Selezione' button and a checkbox for 'Nessun codice AIC'; 'Allega Dossier' with 'Nome Documento' and 'Allegato' text boxes and 'Browse...' buttons; and 'Inserimento Note' with an 'Inserisci' button. At the bottom, there are 'Salva' and 'Indietro' buttons.

Picture 4: Create a new dossier

The section “Acquisizione Application Form” allows to attach the previously generated application form files (the Electronic Application Form in PDF format and the Electronic Application Form in XML format)

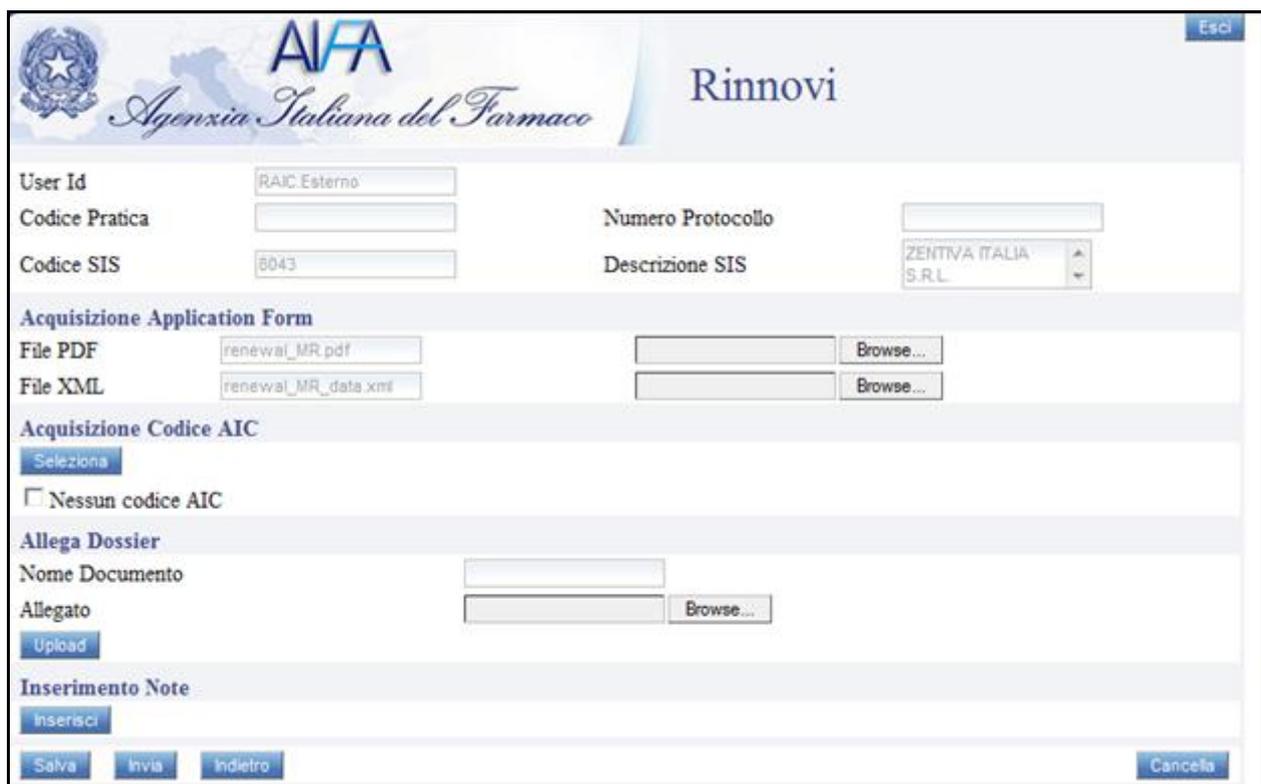
Then click the button “Salva”.

This step is mandatory to activate the subsequent sections. After clicking the button “Salva”, the following message will be displayed.



Picture 5: Saving a dossier

Press "OK" on the notification message and the following window will appear:



Picture 6: New Dossier 2

After saving the Electronic Application Form the following sections will be enabled:

- Acquisizione Codici AIC (Acquisition Medicinal Product codes)
- Allega Dossier (Attach Dossier)
- Inserimento Note (Note Insertion)

3.2.1 Acquisizione codice AIC (Acquisition Medicinal Product codes)

This section allows you to choose one or more AIC codes (Medicinal Product codes) to be inserted in the AIC Dossier . the above cited insertion has to be done by accessing the medicinal management page, that is viewable by clicking the "Select" button.

In order to add a new code AIC, you must first select the product , by using the drop-down list.

The user can only enter the drugs displayed by the system.

To save the selected AIC codes, please click on the button “OK”.

If the medicine is not yet associated with an AIC code , click on the check-box "No code AIC."

The result is summarized in the following screen:

<input type="checkbox"/>	Codice	Descrizione
<input checked="" type="checkbox"/>	016	* 5 MG COMPRESSE * 1 COMPRESA IN BLISTER AL/AL
<input checked="" type="checkbox"/>	028	* 5 MG COMPRESSE * 2 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	030	* 5 MG COMPRESSE * 3 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	042	* 5 MG COMPRESSE * 6 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	055	* 5 MG COMPRESSE * 12 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	067	* 5 MG COMPRESSE * 18 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	079	* 10 MG COMPRESSE * 1 COMPRESA IN BLISTER AL/AL
<input type="checkbox"/>	081	* 10 MG COMPRESSE * 2 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	093	* 10 MG COMPRESSE * 3 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	105	* 10 MG COMPRESSE * 6 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	117	* 10 MG COMPRESSE * 12 COMPRESSE IN BLISTER AL/AL
<input type="checkbox"/>	129	* 10 MG COMPRESSE * 18 COMPRESSE IN BLISTER AL/AL

Picture 7: Acquisizione AIC (Acquisition Medicinal Product codes)

3.2.2 Allega dossier (Attach Dossier)

The "Allega Dossier" section allows you to attach one or more documents to the file. You can enter a name by using the text box labeled "Nome Documento". Then choose the file to be uploaded by pressing the "Scegli file" button. To complete this task you have to click on the "Upload" button. The result is shown in picture 8:

Nome Documento	Allegato
Documento 1	NAZ_Tipo_2.pdf

Figura 8: Allega Dossier (Attach Dossier)

If you want to delete one of the uploaded file, just click on the button 

3.2.3 Inserimento Note (Notes insertion)

This section allows the Pharmaceutical Company to insert the following information for every type of production office :

- Officina\Fase: Batch Release Prodotto finito (Batch Release Finished Product)
Indicate the packages which are carried out at this stage and any possible NOTES
- Officina\Fase: For blood products and vaccines
Indicate the packages which are carried out at this stage and any possible NOTES
- Officina\Fase: batch control/testing
Indicate the packages which are carried out at this stage and any possible NOTES
- Officina\Fase: medicinal product
Indicate the packages which are carried out at this stage.
- Officina: active substance(s)
Indicate the Active substances and the production steps.

The following picture shows an example of the note insertion.

The Company field and address are precompiled. This information is retrieved from the file saved in the " Acquisizione Application Form " and specifically within the XML file.

Officina di produzione del prodotto		
Azienda	Indirizzo	Note
MEDICINAL PRODUCT-NAME	medicinal product-Address	medicinal product - Note
Officina di produzione del principio		
Azienda	Indirizzo	Note
ACTIVE SUBSTANCE - NAME	ACTIVE SUBSTANCE-ADDRESS	
Batch Release		
Azienda	Indirizzo	Note
BATCH RELEASE-COMPANY NAME	BATCH RELEASE-ADDRESS	
BATCH RELEASE-COMPANY NAME2	BATCH RELEASE-COMPANY ADDRESS2	
Contact Vaccine		
Azienda	Indirizzo	Note
BATCH RELEASE-LABORATORY NAME1	BATCH RELEASE-ADDRESS1	
Batch Testing		
Azienda	Indirizzo	Note
BATCH CONTROL/TESTING-NAME	BATCH CONTROL/TESTING-ADDRESS	

Salva Indietro

Figura 9: NOTES

The insertion in the field “Note” is mandatory to enable to the Italian Medicines Agency to evaluate the renewal requests.

3.2.4 Send file

After having filled all the required fields for the variation file, you will be able to send it to AIFA by clicking on the button “Invia”.

This function allows the user to:

- Obtain a file number.
- Obtain a protocol number.
- Send the renewal application to the Italian Medicines Agency.

The Applicant must print the displayed page and attach it to the documents to be sent to the Italian Medicines Agency.

The screenshot shows the AIFA 'Rinnovi' interface. At the top left is the AIFA logo and the text 'Agenzia Italiana del Farmaco'. The page title is 'Rinnovi'. The form contains several input fields: 'User Id' (value: PAC-Enzima), 'Codice Pratica' (value: P096902013), 'Codice SIS' (value: 0043), 'Numero Protocollo' (value: 123456789), and 'Descrizione SIS' (value: ZENTIVA ITALIA S.R.L.). Below these is the 'Acquisizione Application Form' section with 'File PDF' (value: rinnovo_1018.pdf) and 'File XML' (value: rinnovo_1018_580.xml), each with a 'Carica' button. The 'Codice Farmaco' section lists two items: '041462 BISOPROLOLO ZENTIVA ITALIA' and '042064 RIZATRIPTAN ZENTIVA'. A 'Stampa' button is at the bottom right. A modal dialog box is centered on the screen with the text: 'Stampare la pagina corrente come ricevuta ed allegarla alla documentazione cartacea da inviare all'AIFA.' and an 'OK' button.

Figura 10: Send Dossier

3.3 Ricerca pratica

By using the Search feature, you can search dossier using the following criteria:

- Codice pratica (Dossier Number)
- Numero protocollo (Protocol Number)
- Codice AIC (Medicinal Product codes)
- Stato Pratica (Dossier Status)
- Data Inizio/Fine protocollo (start/end protocol date)

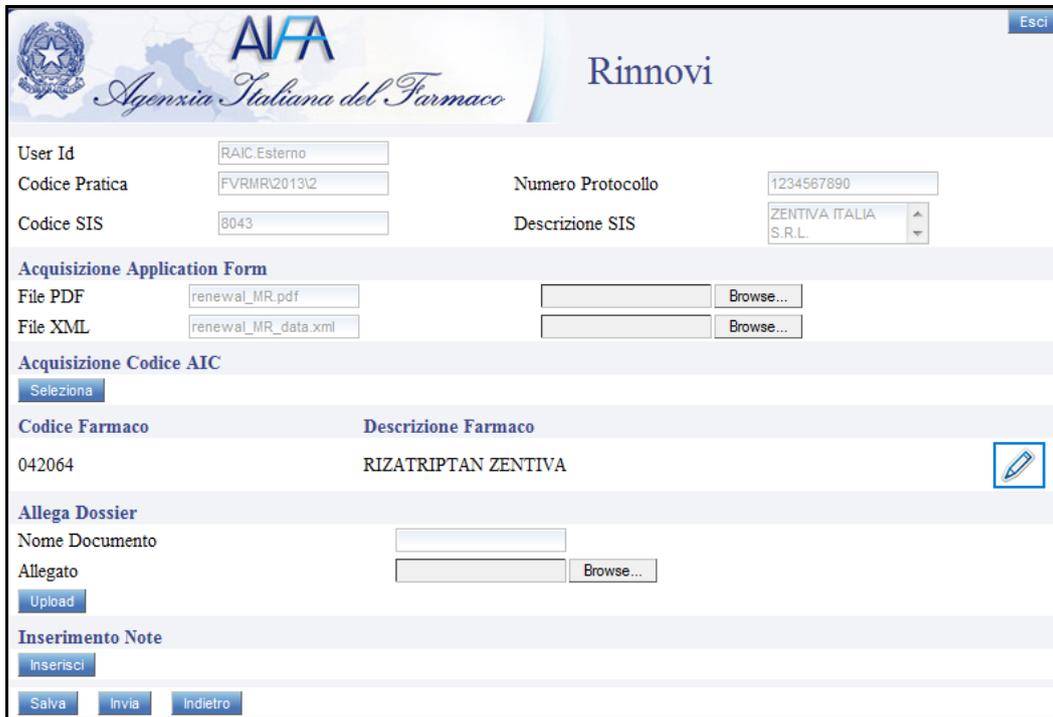
Figura 11 : Search Dossier (a)

The outcome of a correct search is as follows:

Codice Pratica	Numero Protocollo	Data Protocollo	Stato Pratica
			In lavorazione
			In lavorazione
FVRMC\2013\1	1234567890	29-mar-2013	Trasmessa
FVRMR\2013\1	1234567890	2-apr-2013	Trasmessa
FVRMR\2013\2	1234567890	3-apr-2013	In revisione azienda

Figura 12: Search Dossier (b)

By clicking on the icon  all the details related to dossier are shown .



The screenshot shows the AIFA Rinnovi application interface. At the top left is the AIFA logo and the text 'Agenzia Italiana del Farmaco'. To the right is the word 'Rinnovi' and an 'Esci' button. Below the header, there are several input fields for user and application information:

User Id	<input type="text" value="RAIC Esterno"/>	Numero Protocollo	<input type="text" value="1234567890"/>
Codice Pratica	<input type="text" value="FVRMR/2013/2"/>	Descrizione SIS	<input type="text" value="ZENTIVA ITALIA S.R.L."/>
Codice SIS	<input type="text" value="8043"/>		

Below this is the 'Acquisizione Application Form' section with two rows of file uploads:

File PDF	<input type="text" value="renewal_MR.pdf"/>	<input type="button" value="Browse..."/>
File XML	<input type="text" value="renewal_MR_data.xml"/>	<input type="button" value="Browse..."/>

Next is the 'Acquisizione Codice AIC' section with a 'Seleziona' button. Below that is a table for 'Codice Farmaco' and 'Descrizione Farmaco':

Codice Farmaco	Descrizione Farmaco	
042064	RIZATRIPTAN ZENTIVA	<input type="button" value="Edit"/>

Below the table is the 'Allega Dossier' section with 'Nome Documento' and 'Allegato' fields, each with a 'Browse...' button and an 'Upload' button. At the bottom is the 'Inserimento Note' section with an 'Inserisci' button. At the very bottom are three buttons: 'Salva', 'Invia', and 'Indietro'.

Figura 13: Dossier Details

3.4 Edit file

Edit function allows the company for adding additional documentation to a dossier previously sent to Italian Medicines Agency.

A dossier can be modified by the Pharmaceutical Company only if its status is :

- In Lavorazione (under processing)
- In Revisione Azienda (In Review)

The Pharmaceutical Company can only edit the following fields :

- Acquisizione Application Form (Acquisition Application form)
- Acquisizione Codice AIC (Acquisition Medicinal Product codes)
- Allega Dossier (Attach Dossier)
- Inserimento Note (Note Insertion)

As shown in the following page :

The screenshot displays the AIFA 'Rinnovi' interface. At the top left is the AIFA logo and 'Agenzia Italiana del Farmaco'. The page title is 'Rinnovi'. The form contains the following fields and sections:

- User Id:** RAIC Esterno
- Codice Pratica:** FVRMR2013/2
- Numero Protocollo:** 1234567890
- Codice SIS:** 8043
- Descrizione SIS:** ZENTIVA ITALIA S.R.L.
- Acquisizione Application Form:** Includes 'File PDF' (renewal_MR.pdf) and 'File XML' (renewal_MR_data.xml) with 'Browse...' buttons.
- Acquisizione Codice AIC:** Includes a 'Seleziona' button and a table with columns 'Codice Farmaco' (042064) and 'Descrizione Farmaco' (RIZATRIPTAN ZENTIVA). A pencil icon is next to the description.
- Allega Dossier:** Includes 'Nome Documento' and 'Allegato' fields with 'Browse...' buttons and an 'Upload' button.
- Inserimento Note:** Includes an 'Inserisci' button.
- Bottom buttons:** Salva, Invia, Indietro.

Figura 14: Edit dossier

If the Pharmaceutical company needs to reacquire the Application form of a dossier with the status (Revsione Azienda (In Review)), the system will automatically load the previously uploaded application form in "Allega Dossier" section .

The file will be renamed as shown in the following picture

The screenshot shows the 'Rinnovi' (Renewals) section of the AIFA website. The header includes the AIFA logo and the text 'Rinnovi'. Below the header, there are several input fields for user identification and protocol details:

- User Id: RAIC Esterno
- Codice Pratica: FVRMRI20132
- Codice SIS: 8043
- Numero Protocollo: 1234567890
- Descrizione SIS: ZENTIVA ITALIA S.R.L.

Next is the 'Acquisizione Application Form' section, which contains two rows for file uploads:

- File PDF: renewal_MR.pdf (with a 'Browse...' button)
- File XML: renewal_MR_data.xml (with a 'Browse...' button)

The 'Acquisizione Codice AIC' section features a 'Seleziona' button and a checkbox labeled 'Nessun codice AIC'.

The 'Allega Dossier' section includes a 'Nome Documento' field, an 'Allegato' field with a 'Browse...' button, and an 'Upload' button.

Below this is a table of attached documents:

Nome Documento	Allegato
renewal_MR_old_03_04_2013.pdf	renewal_MR_old_03_04_2013.pdf

The 'Inserimento Note' section has an 'Inserisci' button. At the bottom of the form are three buttons: 'Salva', 'Invia', and 'Indietro'.

Figura 15: Edit dossier 2

After entering the required documentation, the Pharmaceutical Company must click the SEND button to submit the dossier integration to the Italian Medicines Agency as well as acquire a new Protocol number.

The Company must print the displayed page and attach it to the documents to be sent to the Italian Medicines Agency.

4 Support

For information and support requests , please contact the Italian Medicines Agency's Help Desk :

- **Email: helpdesk@aifa.gov.it**
- **Tel: 06/59784949**
- **Fax: 06/59784948**

Please note that the operators are available Monday to Friday from 9:00 to 18:00.