

LIAISON[®] ASYc – Calculator Software

User Manual

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LIAISON[®] asy^c



The Diagnostic Specialist

DISCLAIMER

The information contained in this manual is based on experience and knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

DiaSorin is not liable for any loss or damage, including specific damages and those resulting from the use or misuse of the contained information, due to negligence or other faults.

This document refers to access at the highest level. Working with lower level access may cause a lack of some functionalities.

LIAISON® ASYc may only be used by authorized, specifically trained personnel.

This manual cannot be considered substitutive of the official training provided by DiaSorin.

In the event of problems or doubts about using the product, contact your local technical service representative.

The previous legal manufacturer of **LIAISON® ASYc** was DiaSorin S.p.A.



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REVISION INDEX

Revision	Impacted chapter/section	Description of change(s)
B	DISCLAIMER section in second page §1.3 Intellectual property rights §1.4 Authorization and disclaimers about Documentation §1.5 DiaSorin warranty §1.7.1 General safety §1.7.2 Liability §1.8 User safety §1.9.1 General requirements	Modified legal manufacturer name in “DiaSorin Italia S.p.A.”
B	DISCLAIMER section in second page	Added information about previous legal manufacturer.



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1 Introduction

The purpose of this manual is to assist the laboratory user in using **LIAISON[®] ASYc**.

The information in this manual is strictly intended for authorized personnel trained in the use of **LIAISON[®] ASYc**.

1.1 Description

The product described in this document is an In Vitro Medical-Diagnostic device (IVD) intended for professional use. The personal computer on which the application is installed and the other hardware components are not part of this medical device.

1.1.1 Intended use

LIAISON[®] ASYc is an optional software program designed to calculate a diagnostic result by processing the data generated by the relative **LIAISON[®]** assays in accordance with the instructions for use of the assay.

LIAISON[®] ASYc combines the individual results of an analysis, using an algorithm approved and specific for each analysis, to obtain the final result relative to the patient (e.g. positive, negative or indeterminate).

LIAISON[®] ASYc interfaces with Middleware or Laboratory Information Systems (LIS) to receive the individual results of the tests generated by analyzers of the **LIAISON[®]** family, and to provide the final result without any interaction with the end-user.

LIAISON[®] ASYc is a device that never enters into contact with people (patients or operators) and it is classified as autonomous medical software for *In Vitro* diagnostics.

For professional use only.

1.2 Customer Service

If you have any questions about **LIAISON[®] ASYc**, please contact your local DiaSorin Customer Service.

1.3 Intellectual property rights

LIAISON[®] ASYc and the system documentation are protected by copyright laws. All rights are reserved. This manual was developed only for use with **LIAISON[®] ASYc** systems.

The information, documents and relative illustrations published herein (the “Documentation” or “Document”) are the sole property of DiaSorin Italia S.p.A. Using the information is authorized provided that:

- the Documentation is used in relation to the operation of DiaSorin products by qualified personnel, or for informational purposes only;
- the copyright note is indicated on all the copies;
- the Documentation is not modified in any way;

no illustrations are used separately from the accompanying text.

1.4 Authorization and disclaimers about Documentation

LIAISON[®] ASYc is an in vitro medical-diagnostic device (IVD) intended for professional use in clinical analysis laboratories and must only be used by authorized and specially trained personnel.

This manual of instructions for use provides indications on using the application functionalities; the manual cannot, however, be considered substitutive of training sessions supported by DiaSorin.

The information contained in this manual is based on experience and knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

Should **LIAISON[®] ASYc** be used differently from what is described in this manual, the functionalities provided by the system, its performance and data security may become compromised. DiaSorin is not liable for any damages resulting from the misuse of the contained information, due to negligence or other faults.

Under no circumstances shall the manufacturer and/or distributor of the application software be held liable for malfunctions or data corruption due to the propagation of computer viruses in the host system.

In the event of problems or doubts regarding the use of the system, contact the technical service.

1.5 DiaSorin warranty

DiaSorin Italia S.p.A. makes no representations or warranties of any kind or nature with respect to the Documentation.

DiaSorin Italia S.p.A. disclaims all representations and warranties, whether express or implied, created by law, contract or otherwise, including, among others, any warranties of merchantability, fitness for a particular purpose, title or non-infringement.

In no event shall DiaSorin Italia S.p.A. be liable for damages of any kind or nature, including, by way of example, direct, indirect, special (including loss of profit), consequential or incidental damages arising from or in connection with the existence or use of the information, regardless of whether DiaSorin Italia S.p.A. has been advised as to the possibility of such damages.

1.6 Messages, notes and symbols

The symbols described below are used in this manual and may be downloaded with the installation files.

1.6.1 Visualization of warnings and notes

CAUTION



The signal word **"Caution"** and a relating symbol point to a potential danger/problem.

Non-compliance with the safety instructions may cause faults in the software functionalities. Incorrect processing or data corruption cannot be excluded.

CAUTION

The signal word **"Caution"** points to a potential problem. Non-compliance with the instructions provided may cause data processing errors or data losses.

NOTE

The signal word **"Note"** points to a potential problem. The non-observance of notes can result in an adverse effect on the system function.

1 Introduction

1.6.2 Symbols used on the device label

	Manufacturer
	Date of manufacture
	In vitro medical-diagnostic device
	CE mark
	Catalogue number
	Serial number
	Consult instructions for use

1.7 Safety instructions

1.7.1 General safety

The following safety instructions must be observed at all times, both before and during operation of the system.

The Instructions for use are provided for user safety and contain important information for using the system described.

- Before using **LIAISON® ASYc**, read the following safety explanations carefully. Users must be trained before being allowed to use the system.
- The Instructions for use must always be kept available near the system.
- For maintaining safety, do not modify or replace the files and folders created during the installation of **LIAISON® ASYc**. Installation and service of the system or changes in the installation may never be performed by non-authorized persons not approved by DiaSorin Italia S.p.A.
- Do not perform any operation, or use any function not described in the Instructions for use. In the event of problems regarding the system, contact DiaSorin Italia S.p.A. or an authorized representative.
- The cautions indicated in the **LIAISON® ASYc** device manual are prepared after careful examination; however, phenomenon beyond prediction may occur. When using the device, correct compliance with the instructions is essential.

The Instructions for use must be accessible to the user at all times.

NOTE

To guarantee the full operational conditions of the **LIAISON® ASYc** system, it is mandatory to allow DiaSorin Italia S.p.A. personnel, or any field service authorized representative to perform all the necessary scheduled and unscheduled interventions.

CAUTION



Failure to adhere to the IFU may result in damage to the system or adversely affect the assay result.

1 Introduction

1.7.2 Liability

The **LIAISON[®] ASYc** device was developed in accordance with the safety requirements for in vitro medical-diagnostic devices. It is the user's responsibility to comply with local regulations and laboratory procedures for the installation and operation of the device.

The manufacturer has done everything possible to guarantee the safe operation of the device. The system is tested and approved by the manufacturer and supplied in a condition that enables its safe and reliable operation.

The information contained in these Instructions for use is based on experience and knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

DiaSorin is not liable for any data losses or corruption, including damages resulting from the misuse of the contained information, due to negligence or other faults on the part of personnel.

- The device may only be used in compliance with its intended use.
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

CAUTION



Improper use of the system can lead to an incorrect interpretation of the results, corrupt or cause the loss of the data in the system.

1.7.3 Cautions on electromagnetic wave interference

1.7.3.1 Electromagnetic wave interference generated by **LIAISON[®] ASYc** to other equipment

LIAISON[®] ASYc is a software device installed on third party hardware components. For more information on electromagnetic wave interference generated by hardware components, refer to the documentation provided by the hardware manufacturer.

1.7.3.2 Electromagnetic wave interference on LIAISON[®] ASYc that may be generated by other devices

If LIAISON[®] ASYc is used near other devices that generate strong electromagnetic wave interference, the disturbances could cause malfunctions to the hardware system on which it is installed.

Refer to the documentation of the hardware supplier for more information on electromagnetic wave interference.

1.8 User safety

The aim of this section is to bring to the user's attention the status of residual risks despite the safe design measures, safeguarding and complementary protective measures adopted by the manufacturer to lower the risks to an acceptable level.

The user must carefully read this manual to understand the residual risks and learn how to work safely with the LIAISON[®] ASYc device.

If further clarification is needed, contacting the local DiaSorin representative is recommended.

User warning: any serious incident that occurs in relation to the device must be notified to DiaSorin Italia S.p.A. and to the competent authority of the EU member state in which the user and/or patient lives.

1.8.1 Definitions

- (a) "risk" means the possibility that damage may arise as the consequence of a hazardous situation;
- (b) "user" means the person operating the device;
- (c) "intended use" means the use of the instrument in accordance with the information provided in the instructions for use;
- (d) "reasonably foreseeable misuse" means the use of the device in a way not intended in the instructions for use, but which may result from readily predictable human behavior.

1 Introduction

1.8.2 Inherent safe design and manufacturing process

The instrument has been designed and manufactured applying a risk management process based upon ISO standard 14971. The management of the risk is configured according to the instructions set forth in the ISO 13485 standard, and the quality criteria.

By the application of the standard, through an iterative risk analysis process, the manufacturer has:

- determined the limits of the device, which include the unintended use and any reasonably foreseeable misuse;
- identified the hazards and the associated hazardous situations that can be generated by the use of the device;
- estimated the risks for hazardous situations, taking into account the severity of the potential harm and the probability of its occurrence by the application of an appropriate FMEA (Failure Mode and Effect Analysis) methodology;
- evaluated the risks to determine whether risk reduction is required;
- reduced the risk by identifying, implementing and verifying the effectiveness of appropriate risk control measures.

The process described above will be maintained by the manufacturer until the retirement of the **LIAISON[®] ASYc** device.

Where possible, the instrument has been designed and constructed to prevent abnormal use if such use would create a risk.

The instructions have to be carefully read, paying attention to all warnings, taking into account the way the device has to be operated and which are the abnormal uses forbidden.

1.9 Operational precautions and limitations

This section describes the operational requirements, precautions, and limitations of the device to ensure accurate assay results.

User must follow these requirements to help ensure proper system performance.

Not following the requirements and precautions provided can impact the system and adversely affect assay results.

1.9.1 General requirements

- To ensure continuity of operation, using an uninterruptible power supply is recommended.
- Do not carry out any servicing operations on the system that are not specified in the documentation provided by DiaSorin Italia S.p.A.

1.9.2 System requirements

For LIAISON[®] ASYc to be installed, the minimum requirements listed below must be met:

Hardware	Standard PC with: • quad core processor or higher • at least 8 Gb RAM
Operating System	• Windows 10 Professional 64 bit • Windows Server 2016 • Windows Server 2019
Database	SQL Server 2019

NOTE

If not present, SQL Server is installed during installation.

CAUTION



If the product is installed on a non-compatible operating system, the following risks are possible:

- The web services provided by the application may not work, so the middleware/LIS will not be able to select them;
- The graphic interface of the product may not work, so it will not be possible to modify the general product configuration and the configuration of a profile.

CAUTION



If the product is linked to a database other than the one installed by the installation procedure, the application will not work, the launch procedure will be aborted and an error message will appear.

1 Introduction

1.9.3 Compatible browsers

Although **LIAISON[®] ASYc** can be used on other browsers or other browser versions, only those listed below have been tested.

Browser	Version	LIAISON [®] ASYc 1.0.0
Chrome	87	x
Firefox	84	x
Edge	42	x

CAUTION



If the graphic interface of the product is accessed using a non-compatible browser, it may not work, so it will not be possible to modify the general product configuration and the configuration of a profile.

CAUTION



Improper use of the system can lead to an incorrect interpretation of the results, corrupt or cause the loss of the data in the system.

1.9.4 System operation

1.9.4.1 Precautions and requirements before operation

Before beginning to operate on the system, the end-user must:

- Read this entire manual to fully understand the functionalities of the system and the associated risks.
- Check that the device is not giving any alarm signals.

1.9.4.2 Precautions during operation

- Do not disconnect any electrical connection during operation.
- Check the system and adopt the necessary countermeasures if warning messages appear.

1.9.5 Limits on the interpretation of the results

Any result interpreted by **LIAISON[®] ASYc** must not be used as medical advice or service without the approval of authorized medical personnel. Results must be used with other clinical data, such as symptoms, other test results, patient history, clinical data, information available from clinical evaluations, and other diagnostic procedures.

1.10 System maintenance

The end-user is responsible for maintaining the PC and the environment that host **LIAISON[®] ASYc**, in terms of both the hardware components and the basic software (application of security patches, antivirus installation/updating, data backups, account maintenance).

Any updates of the hardware components or the basic software that breach the minimum requirements listed in section 1.9.2 are forbidden.

1.11 System installation

If the system needs to be installed or updated, the end-user must contact the local DiaSorin technical service representative.

CAUTION

Installation

LIAISON[®] ASYc may only be installed by authorized, specifically trained personnel.

1 Introduction

1.12 System removal

If the system needs to be moved or removed, the end-user must contact the local DiaSorin technical service representative.

CAUTION



Removal

LIAISON[®] ASYc must be removed by authorized technical service personnel.

2 Safety measures

2.1 Introduction

LIAISON[®] ASYc was designed to be used in a controlled environment. Only trained and authorized users may access the application. Despite this, the risk of unauthorized access to the system exists, which can potentially result in loss, corruption or unauthorized disclosure of data, or system malfunctions.

The device was designed and manufactured applying a risk management process regarding cybersecurity. Through an iterative risk analysis process, the manufacturer has:

- determined the limits of the device, which include the unintended use and any reasonably foreseeable misuse;
- identified the safety vulnerabilities and the risk situations associated with usage of the device;
- assessed the risk of hazardous situations, taking into consideration the severity of the potential damage and the probability of its occurrence;
- evaluated the risks to determine whether risk reduction is required;
- reduced the risk by identifying, implementing and verifying the effectiveness of appropriate risk control measures.

The process described above will be maintained by the manufacturer until the retirement of the **LIAISON[®] ASYc** device.

The end-user is responsible for maintaining the host PC updated with the latest security patches issued for the software installed thereon (e.g. the operating system) and in general for adopting all the good practices for reducing the risk of cyber attacks on the device that hosts the software.

This section describes the criteria followed by DiaSorin and partners regarding the software updates of the systems installed in end-user environment.

2.2 Unauthorized access

2.2.1 Potential issues

The device is designed to be used only by trained and authorized users, and in conformity with its intended use.

Unauthorized users could access the computer and potentially damage it, without the owner knowing. Consequences may be software and data loss, and corruption or unauthorized disclosure of data.

2.2.2 Protection measures

Access to **LIAISON[®] ASYc** is gained through the use of identifying credentials with different access rights. This allows the application to only be used by authorized personnel, and only for the functionalities for which access is to be granted:

- operating the system, including access to any data, is only possible when typing an authorized user identifier (made of “user name” and “password”), that is unique for each user;
- the “username” is unique. If a user is removed, his/her user name can be reassigned to a new user;
- the “password” must be different from the “username”; it must be minimum 12 characters long and contain at least one number, one symbol and one capital letter;
- for each user, a password duration can be set; within the time frame based on password duration, the system will force the user to change the password;
- every user may change their own login password;
- it's possible to define a session expiration time, i.e. a time interval after which the system logs off the current user;
- to avoid key search attacks, after three failed login attempts, the procedure prevents the user from logging in for a minute;
- during system installation, a temporary password is provided, which the user must change the first time he/she logs in.

In order to select the REST web services of **LIAISON[®] ASYc**, client systems must pass an authentication phase. To access the authentication phase, Middleware and LIS have a “secret” access key. If several client systems access the same installation of **LIAISON[®] ASYc**, each of them will use a different secret access key.

Following authentication, **LIAISON[®] ASYc** will issue each client with a Token in the form of a cookie. Only systems with the Token are authorized to select the Web Services of **LIAISON[®] ASYc** to request the application of a specific algorithm. The received Token must be “attached” to every subsequent service request by the Middleware/LIS and evaluated by **LIAISON[®] ASYc**. The Tokens have an expiry that can be configured by Admin users. After the expiry date, the Middleware/LIS must request new Tokens from **LIAISON[®] ASYc**.

2.3 Malware

2.3.1 Potential issues

Usage of the computer on which **LIAISON[®] ASYc** is installed could lead to voluntary or involuntary introduction of malicious software, like viruses, worms, spyware. This malicious software (also called malware) is designed to infiltrate and potentially damage a computer system without the owner's informed consent. Potential consequences include loss, corruption or unauthorized disclosure of data.

Malware can be introduced:

- via the LAN network;
- via removable USB storage devices;
- via optical media (CDs, DVDs, etc.).

2.3.2 Protection measures

The state-of-art, global approach is to provide a network firewall, a personal firewall and an integrated protection tool, generically called ‘anti-malware’.

The end-user is liable for protecting the computer on which **LIAISON[®] ASYc** is installed and it is not part of the supplied medical device.

2 Safety measures

2.4 Unauthorized access via the LAN network

2.4.1 Potential issues

A computer on which **LIAISON[®] ASYc** is installed, connected to a LAN network, may be accessed by unauthorized individuals, causing unpredictable effects on the software. Potential consequences include software and data loss, corruption or unauthorized disclosure of data.

2.4.2 Protection measures

It is good practice to keep the firewall integrated in the operating system active to prevent inbound access from a remote station.

2.5 Privacy

LIAISON[®] ASYc produces analytical results that refer to the health condition of patients.

However, **LIAISON[®] ASYc** does not request patients' personal data in order to carry out its functions and does not manage users' personal data. Therefore, there are no risks that these data will be disclosed.

3 System description

3.1 General description

LIAISON® ASYc is an in vitro medical-diagnostic device (IVD) intended for interfacing with middleware and LIS to manage calculation algorithms useful for interpreting diagnostic data.

LIAISON® ASYc was designed as an application server with the aim of calculating a diagnostic result following the processing of data forwarded by middleware or LIS as obtained from one or more instruments of the **LIAISON®** family.

CAUTION

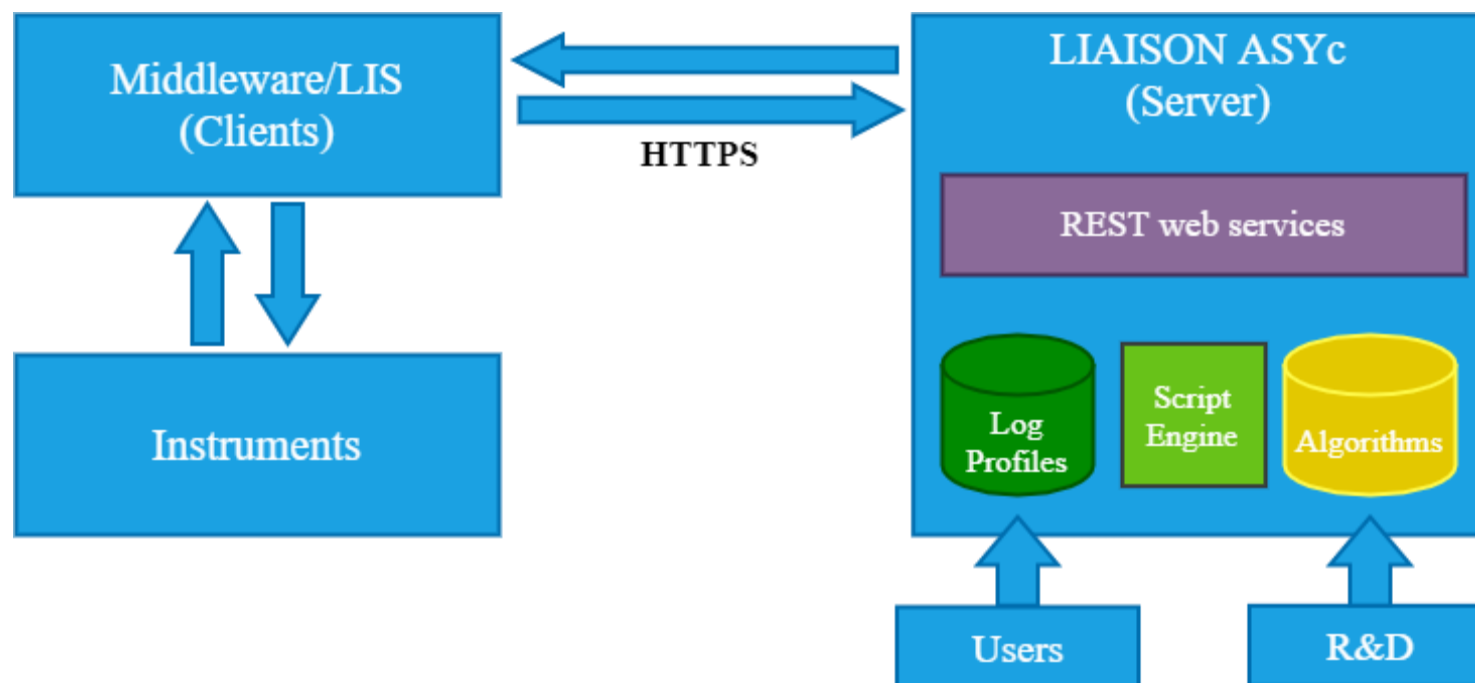


The service cannot be used providing results from different instruments than those belonging to the **LIAISON®** family.

LIAISON® ASYc manages an archive of algorithms, issued by DiaSorin, useful for supporting medical personnel in interpreting results obtained by analytical instrumentation. Each algorithm is contained within a software entity, defined as Profile, which in turn contains the input and output parameters of the algorithm and other parameters useful for interpreting input data.

The middleware/LIS, following the receipt of the results from the instruments, can invoke an active algorithm from those present in the **LIAISON® ASYc** database, using an appropriate web service. To this end, following authentication, the middleware makes an HTTPS request, conveying the input parameters received from the instruments. **LIAISON® ASYc** processes the request, applies the algorithm and provides the middleware with the output of the invoked algorithm.

3 System description



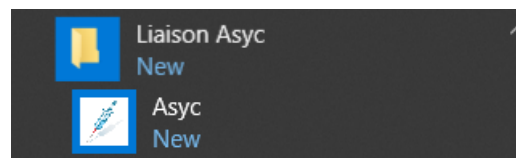
LIAISON[®] ASYc has a WEB interface that enables users to configure the product and inspect its behavior through the LOGs, based on the access rights assigned to each user.

3.2 Launch and access

LIAISON[®] ASYc is a Windows service, so it is configured to be launched automatically when the computer on which it is installed is started.

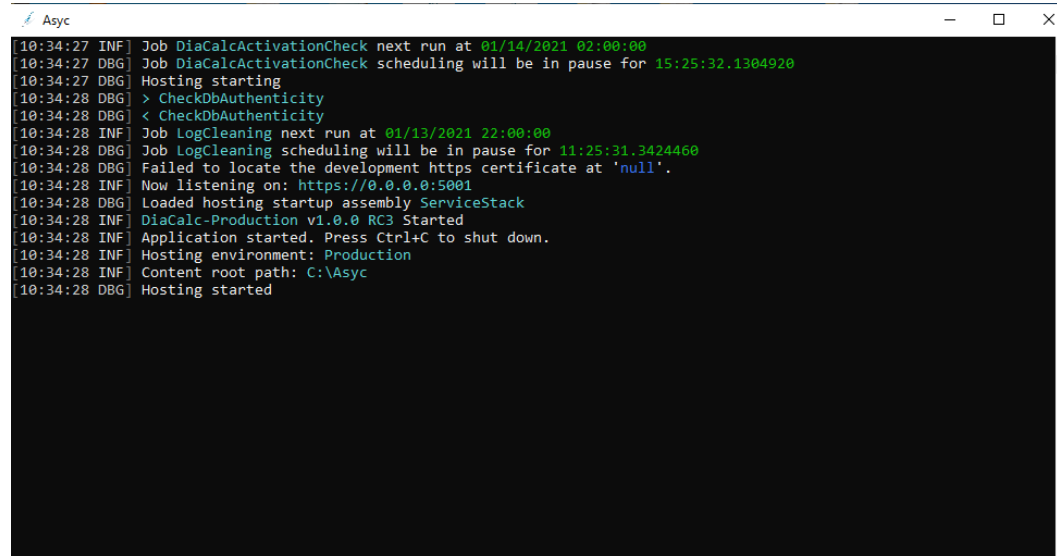
If **LIAISON[®] ASYc** needs to be launched manually, carry out one of the following actions:

- Click on the ASYc_Start icon on the desktop of the PC, only present if the creation of shortcuts was enabled in the installation phase. In this case, when the application is launched, this is not notified. Only by logging in to the Login page is it possible to understand whether the application has been correctly launched.
- Click on the link in the start menu.



3 System description

In this case, **LIAISON[®] ASYc** is launched as a console application. If the launch is successful, the console output shown is as follows:



```
10:34:27 INF Job DiaCalcActivationCheck next run at 01/14/2021 02:00:00
10:34:27 DBG Job DiaCalcActivationCheck scheduling will be in pause for 15:25:32.1304920
10:34:27 DBG Hosting starting
10:34:28 DBG > CheckDbAuthenticity
10:34:28 DBG < CheckDbAuthenticity
10:34:28 INF Job LogCleaning next run at 01/13/2021 22:00:00
10:34:28 DBG Job LogCleaning scheduling will be in pause for 11:25:31.3424460
10:34:28 DBG Failed to locate the development https certificate at 'null'.
10:34:28 INF Now listening on: https://0.0.0.0:5001
10:34:28 DBG Loaded hosting startup assembly ServiceStack
10:34:28 INF DiaCalc-Production v1.0.0 RC3 Started
10:34:28 INF Application started. Press Ctrl+C to shut down.
10:34:28 INF Hosting environment: Production
10:34:28 INF Content root path: C:\Asyc
10:34:28 DBG Hosting started
```

NOTE

ATTENTION: closing this window arrests the application. See section 3.4.

To interact with the graphic interface of **LIAISON[®] ASYc**, access the Login screen from the browser, entering the URL <https://<nomeReteServer>:5001>, where <nomeReteServer> is the full name of the host server of **LIAISON[®] ASYc** and 5001 is the value set in the configuration phase for the **TCP port** parameter.

NOTE

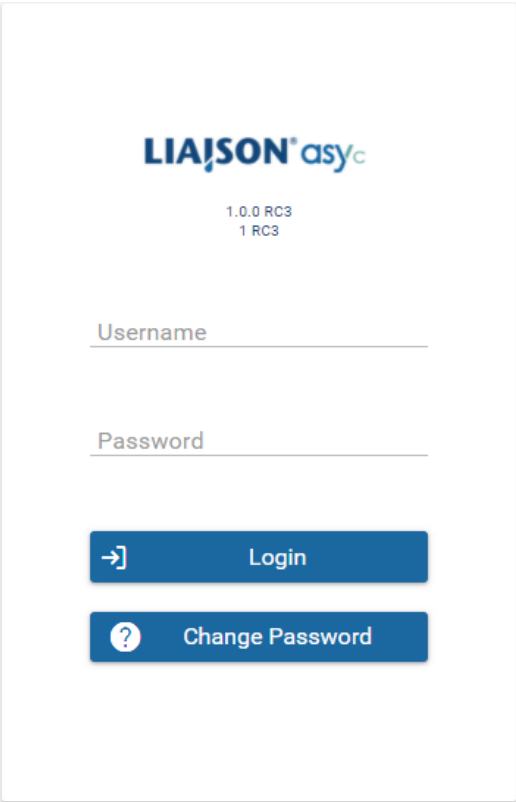
At the first launch, **LIAISON[®] ASYc** saves the name of the server network in the file *env.js* in the folder C:\LIAISON[®] ASYc\wwwroot.

NOTE

When the pc is started, **LIAISON[®] ASYc** launches automatically.

To log in, proceed as follows:

- Enter **Username** and **Password** in the appropriate fields.



- Click on the **Login** button.

NOTE

When a new user logs in for the first time, **LIAISON[®] ASYc** obligatorily requires the password to be changed.

3 System description

LIAISON[®] ASYc manages access rights for the end-user, who is enabled to carry out the following operations:

- Access the software by logging in
- Enable or disable the Profiles and view their status
- View the product label
- Launch and arrest the software.

The product can only be installed and configured by users with superior access rights (*Admin/FSE*).

3.3 Change password

The first time the end-user logs in, he/she must change the assigned temporary password.

Having inserted **Username** and **Password** and clicked on **Login**, the end-user is directed to the **Change Password** page.

To change the password, proceed as follows:

- Fill in the following fields:
 - **Username**: insert the username of the user who has attempted to log in;
 - **Old Password**: insert the password of the user who has attempted to log in;
 - **New Password**: insert a new password that is different from the username and from the previous password. It must be minimum 12 characters long and contain at least one number, one symbol and one capital letter;
 - **Confirm Password**: confirm the new password inserted.
- Click on **Confirmation**. The end-user will be redirected to the Login page. To log in, insert the updated credentials.



Username: Required

Old Password: Required

New Password: Required

Confirm Password: Required

✓ Confirmation

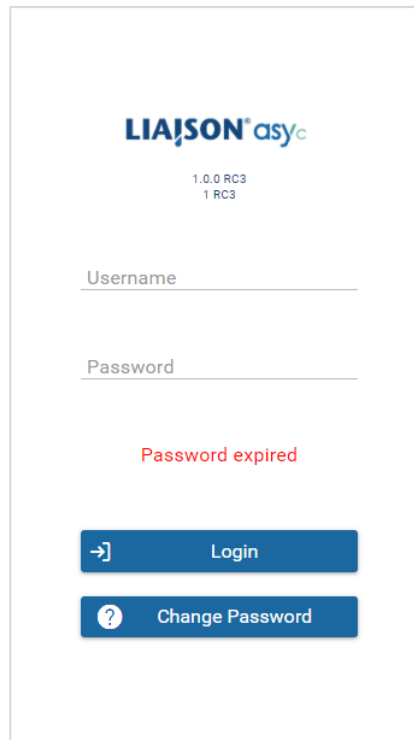
✕ Cancel

3 System description

The end-user may change his/her password at any time. To do so, the procedure is as follows:

- Access the Login page and click on the **Change Password** button.
- Fill in the following fields:
 - **Username**: insert the username;
 - **Old Password**: insert the old password;
 - **New Password**: insert a new password that is different from the username and from the previous password. It must be minimum 12 characters long and contain at least one number, one symbol and one capital letter;
 - **Confirm Password**: confirm the new password inserted;
- Click on **Confirmation**. The end-user will be redirected to the Login page. To log in, insert the updated credentials.

The end-user must also change his/her password when it has expired. Having inserted his/her **Username** and **Password** and clicked on **Login**, the end-user will be notified when his/her password expires.



The screenshot displays the LIAISON® asyc login screen. At the top, the logo 'LIAISON® asyc' is shown, followed by version information '1.0.0 RC3' and '1 RC3'. Below this are two input fields: 'Username' and 'Password'. A red message 'Password expired' is displayed below the password field. At the bottom, there are two buttons: 'Login' (with a right arrow icon) and 'Change Password' (with a question mark icon).

To change the password, proceed as follows:

- Click on the **Change Password** button.
- Fill in the following fields:
 - **Username**: insert the username;
 - **Old Password**: insert the old password;

3 System description

- **New Password:** insert a new password that is different from the username and from the previous password. It must be minimum 12 characters long and contain at least one number, one symbol and one capital letter;
- **Confirm Password:** confirm the new password inserted;
- Click on **Confirmation**. The end-user will be redirected to the Login page. To log in, insert the updated credentials.

NOTE

The validity of the password assigned to the end-user is configured by users with the role *Admin/FSE*.

3.4 Logout and closure of the application

To log out from the browser page of the application, click on the icon  present in the main window, to the right of the username of the logged in end-user. The end-user will then be redirected to the Login page.

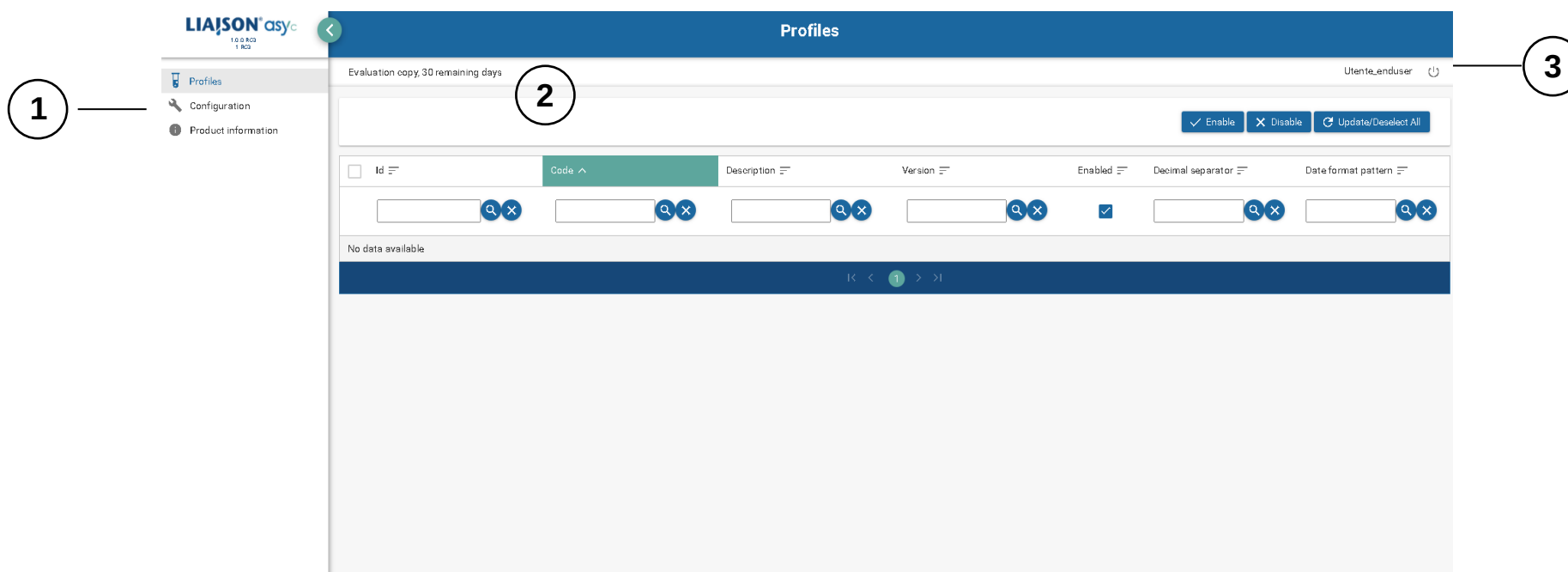
NOTE

During the installation process, the *Admin/FSE* user can configure the period of inactivity after which **LIAISON[®] ASYc** automatically logs out. For more information on activating the automatic logout procedure, refer to Chapter 5 of the manual.

To close **LIAISON[®] ASYc** correctly, having logged out, close the browser and carry out one of the following options:

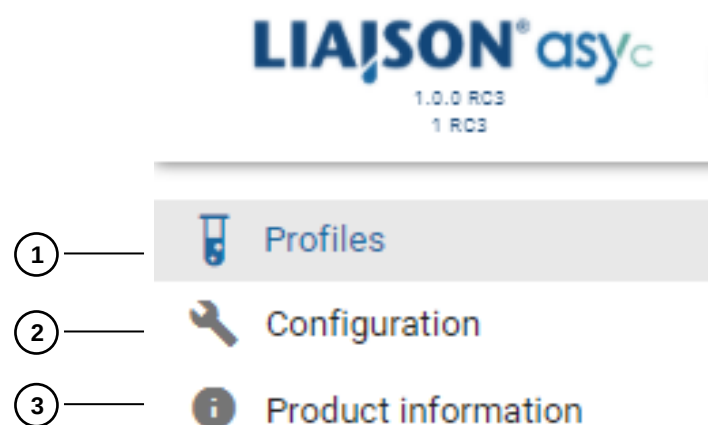
- Click on the ASYc_Stop icon on the desktop, only present if the creation of shortcuts was enabled in the installation phase. The system does not show any messages certifying that the application has been closed.
- If the application has been launched from the link present in the launch menu, press the Ctrl+C buttons on the keyboard, positioning the mouse in the console of **LIAISON[®] ASYc**. The console closes without showing any messages that verify that the application has been closed. The closure of the window that contains the console application through the button present in the title bar or the keyboard shortcuts is equivalent to the Ctrl+C command and causes the arrest of **LIAISON[®] ASYc**.

3.5 User interface



- 1 Side bar for access to the functions of the application.
- 2 Central screen for viewing the page of the selected function in the side bar.
- 3 Indication of the end-user currently logged in and button for logging out.

3 System description



The following pages can be accessed via the side bar:

- | | |
|---|---|
| 1 | Profiles , for viewing and managing the algorithms selected by the middleware/LIS. |
| 2 | Configuration , for configuring the language and viewing the general settings |
| 3 | Product information , for viewing the product label. |

4 Profile Management

LIAISON® ASYc manages the calculation algorithms provided by DiaSorin to middleware and LIS for the purpose of interpreting diagnostic data. The algorithms are contained within objects named Profiles. Profiles may only be designed and approved by DiaSorin personnel (R&D).

The software allows new profiles to be added to users with *Admin/FSE* profiles.

To access the **Profiles** page, click on **Profiles** in the side bar. The page offers the following functions:

Function	Description
Enable	Button that enables one or more selected profiles to be enabled
Disable	Button that enables one or more selected profiles to be disabled
Update/Deselect All	Button to update the list of the profiles and deselect those currently selected.

For each of the visualized fields in the list, the sort function can be applied, by clicking on the name of the interested field.

Additionally, it is also possible to carry out a search in the lists of profiles, by applying a filter to the content of a single column.

Profiles

Evaluation copy, 30 remaining days

Utente_enduser

✓ Enable ✗ Disable ↻ Update/Deinstall All

☐	Id	Code	Description	Version	Enabled	Decimal separator	Date format pattern
☐	10	Profile 1		1.0	✓	,	yyyy-MM-dd HH:mm:ss
☐	11	Profile 2		1.0	✓	.	MM/dd/yyyy hh:mm:ss tt
☐	12	Profile 3		1.0	✓	,	dd.MM.yyyy HH:mm:ss

1 < > >>

4.1 Enable profiles

A profile may be enabled or disabled. When a profile is enabled, the middleware/LIS makes a request and LIAISON[®] ASYc provides the middleware/LIS with the result of the calculation of the corresponding algorithm.

To enable one or more profiles in the list, proceed as follows:

1. Select the profile(s) to be enabled, by clicking in the checkbox in the first column.
2. Click **Enable** in the toolbar of the page.

NOTE

To enable one or more profiles, the user can also select them, right-click on them with the mouse, and then click on **Enable** in the pop-up menu.

4.2 Disable profiles

If a profile is disabled and it is invoked by the middleware/LIS, **LIAISON® ASYc** does not apply the corresponding algorithm to the profile but returns a message error.

To disable one or more profiles in the list, proceed as follows:

1. Select the profile(s) to be disabled, by clicking in the checkbox in the first column.
2. Click **Disable** in the toolbar of the page.

NOTE

To disable one or more profiles, the user can also select them, right-click on them with the mouse, and then click on **Disable** in the pop-up menu.

4.3 Update profile list

After clicking on the **Update/Deselect All** button, the page reloads the content of the list of the profiles and all the records are deselected.

5 Configuration

5.1 Configuration

The **Configuration** page enables the end-user to consult the configuration of **LIAISON[®] ASYc** and change the viewing language.

To access the **Configuration** page, click on **Configuration** in the side bar.

1.0.0 RC3
1 RC3

Configuration

Profiles

Configuration

Product information

Evaluation copy, 30 remaining days

Language	en-US ▼
Decimal separator	Dot (.) ▼
Date and time format	yyyyMMddHHmmss ▼
Automatic logs deletion	☐ Yes ☒ No
Days in the archive	180 ⬆️⬆️
Log deletion time	22:00
Validity of tokens in minutes	1440 ⬆️⬆️
Inactivity timeout in minutes	10 ⬆️⬆️ -1 to disable
TCP port	5001

✓
Confirmation

✕
Cancel

To change the language, proceed as follows:

1. In the **Language** field, select one of the alternatives available in the drop-down menu.
2. Click on the **Confirmation** button at the bottom of the page.

To undo the change, proceed as follows:

1. Click on the **Cancel** button
2. A message requesting confirmation of the action appears:
 - a) Click on **Yes** to undo the change. The **Language** field is populated with the language present before the change.
 - b) Click on **No**, and the page will maintain the change made.

If the end-user clicks on another option in the side bar before having confirmed or canceled the change, a dialog box appears asking him/her to confirm the operation:

- a) Click on **Yes** to change page. In this case, the change of language will not be saved.
- b) Click on **No** to stay on the **Configuration** page. The page maintains the change made but this hasn't been saved.

The **Configuration** page of **LIAISON[®] ASYc** also contains the following fields, which cannot be edited by the end-user:

- **Decimal separator**

The decimal separator to be used to interpret the numerical input parameters, for application to the numerical output parameters when the middleware/LIS does not state this in the transmission of the results. If the middleware/LIS declares a separator, this will have priority over the one specified within the profile, and the one specified in this field.

- **Date and time format**

The date and time format to be used to interpret the date input parameters, for application to the date output parameters when the middleware/LIS does not state this in the transmission of the results. If the middleware/LIS declares a date and time format, this will have priority over the one specified within the profile, and the one specified in this field.

- **Automatic logs deletion**

This indicates whether or not the automatic deletion of the logs is enabled. If it is enabled, the logs will be deleted after a period of time defined in the option **Days in the archive** on this same page.

- **Days in the archive**

The number of days for which the logs have been in the archive. If the radio button at the **Automatic logs deletion** option is set to YES, the logs registered outside the configured period will be deleted.

- **Log deletion time**

The time at which the logs are automatically deleted.

- **Token validity in minutes**

The period of validity of the Token provided to the middleware/LIS for accessing the services. **LIAISON[®] ASYc** will issue to every client, i.e. every user capable of requesting the services provided by the former, a Token in the form of a cookie, which must be attached to the service request. **LIAISON[®] ASYc**, having verified the Token attached to the request, returns the output of the requested service. Upon the expiry of the Token, the client (middleware system/LIS) must again log in to **LIAISON[®] ASYc** to request a new one. If the client makes a request using an expired Token, **LIAISON[®] ASYc** returns an error message notifying the user that the Token is no longer valid.

- **Inactivity timeout in minutes**

The period of inactivity of the connected end-user, after which **LIAISON[®] ASYc** automatically logs out.

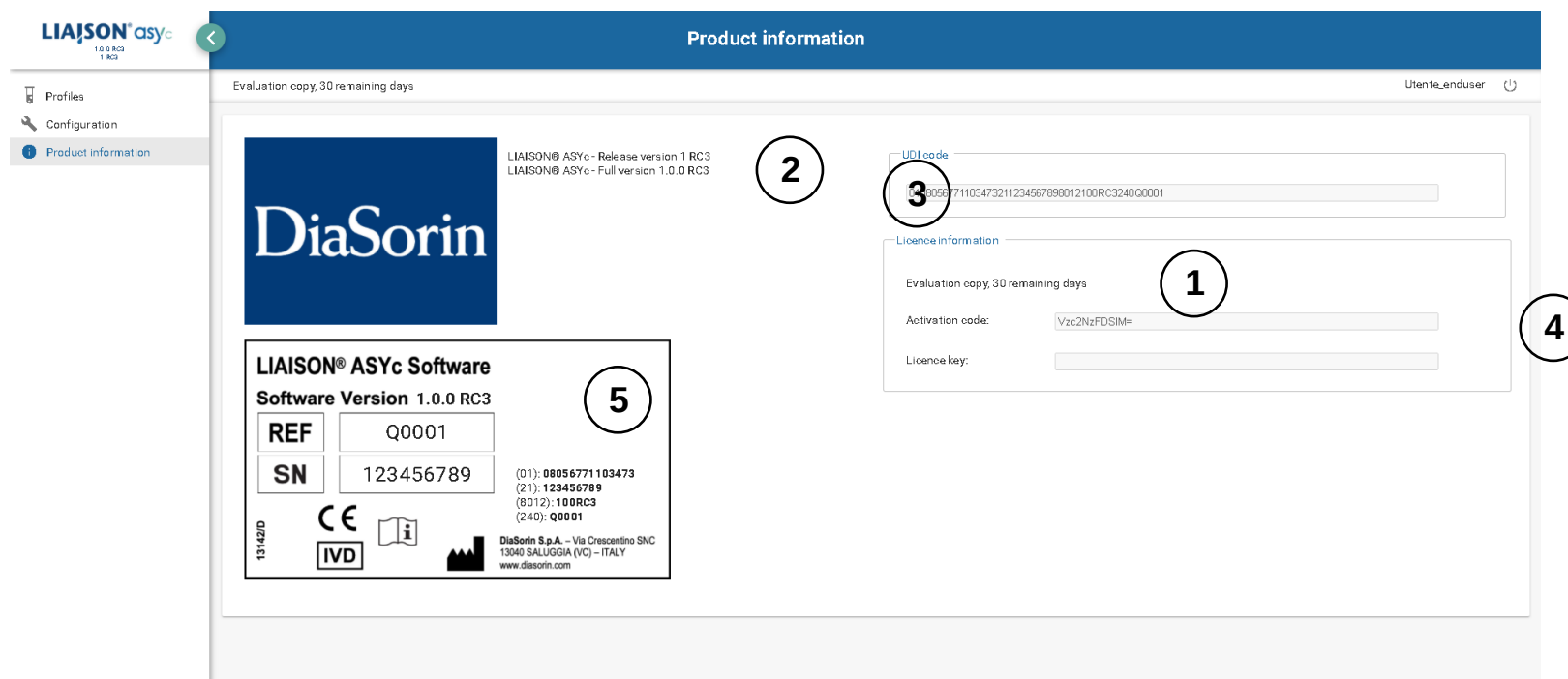
- **TCP port**

This indicates the number of the TCP port on which the service is being listened to and to which the middleware/LIS must direct the request.

6 Product information

The **Product information** page allows the end-user to view the labeling information for LIAISON® ASYc.

To access the **Product information** page, click on **Product information** in the side bar.



LIAISON® asyc
1.0.0 RC3
1 RC3

Product information

Evaluation copy, 30 remaining days

Utente_enduser

DiaSorin

LIAISON® ASYc - Release version 1 RC3
LIAISON® ASYc - Full version 1.0.0 RC3

LIAISON® ASYc Software
Software Version 1.0.0 RC3

REF Q0001

SN 123456789

(01): 08056771103473
(21): 123456789
(012): 100RC3
(240): Q0001

CE IVD

13142/D

DiaSorin S.p.A. - Via Crescentino SNC
13040 SALUGGIA (VC) - ITALY
www.diasorin.com

UDI code
08056771103473211234567898012100RC3240Q0001

Licence information

Evaluation copy, 30 remaining days

Activation code: VzC2NzFDSIM=

Licence key: [redacted]

Utente_enduser

UDI code

0108056771103473211234567898012100RC3240Q0001

Licence information

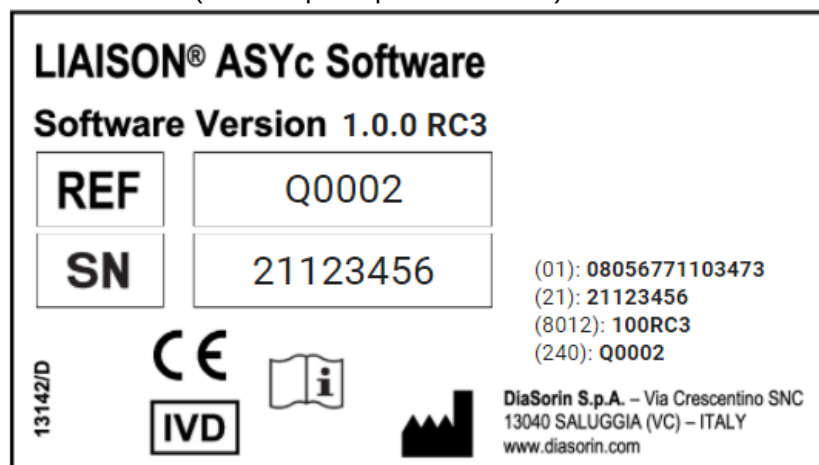
Licence: Activation date 26/01/2021

Activation code: VzC2NzFDSIM=

Licence key: 4532BAE0D2CCB16FDB7E1ABACE367905

The **Product information** page of **LIAISON® ASYc** contains the following information:

1. **Evaluation copy, xx remaining days:** when the product is installed, a 30-day trial version is issued, at the expiry of which **LIAISON® ASYc** may no longer be used. The application can therefore not be launched, and if the middleware/LIS requests the services provided by **LIAISON® ASYc**, this will go unanswered. In the **Product information** page, then, the option *Evaluation copy* appears along with the number of days remaining until the evaluation copy expires.
2. **Product version:** version number (this is updated following a product upgrade).
3. **UDI code:** unique identifier code of the medical device (this is updated following a product upgrade).
4. **Activation code** and **License Key:** the first is to be given to the service personnel in order to proceed in activating the license, the second is only present once the license has been activated.
5. **Product label** (an example is provided below):



6. **License: Activation date :** the license must be activated before the evaluation copy expires. The activation date is only present once the license has been activated in place of the *Evaluation copy* option.

NOTE

The **LIAISON® ASYc** license can only be activated by users with the role *Admin/FSE*.

