

WHALETEQ UDiBar UDI Generator& Label Management System

User Manual

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1 Product Introduction

UDiBar is a unique UDI generator and label management system for medical devices created by WhaleTeq. It can establish a UDI management system that meets the requirements of QMS and ISO13485 in a short time. Its functions include automatic generation of compliant UDI barcodes (EAN13, GS1-128, Data Matrix), tracking and management of UDI labels and barcodes, and a complete database that can be viewed and traced at any time. It also provides operation instructions and 3Q validation templates. Besides, UDiBar offers correspondent format for you to submit to different national databases.

UDiBar is composed of cloud database and software. Users create UDI basic product information, packaging information, etc. on the cloud and get access to it via internal server. Then, users should download the software to conduct barcode generation, label editing, barcode checking, data inquiry and inventory management.



2 Installation Preparation

2.1 System Requirement

User PC should meet the requirements below:

- Windows PC (Microsoft Windows 10 64bits, original version is recommended)
- Microsoft .Net Framework 4.5 to latest version
- System administrator authorization (needed when installing software, activate the program and .Net Framework)
- Database software MySQL Community 8.0
- 1.5 GHz CPU or latest version
- 1GB RAM or latest version
- USB port

2.2 Hardware Requirement

In addition to the computer software, UDiBar needs to be equipped with a labeling machine and a barcode scanner. The following is the current list of devices that can be connected to UDiBar:

1. Labeling machine:

- Windows Driver
- 2. Barcode scanner:
- Support UDI barcode format



2.3 Installing Microsoft .Net Framework 4.7.2 through WhaleTeq device at the first time

Since UDiBar is developed based on Microsoft .Net Framework 4.7.2, please make sure that your operating system has installed Microsoft .Net Framework 4.7.2 or a latest version.

If your computer has not yet installed Microsoft .Net Framework 4.7.2 or a latest version, please download it from the Microsoft official website. Please click <u>here</u> to watch the tutorial video on how to download and install Microsoft .Net Framework (starting at 2:03).



3 Notifications before using UDiBar

3.1 Product Packaging Information

Before using UDiBar, you should sort out the product information that needs to be barcoded, so that you can quickly grasp the packaging information of all levels of the product, so that WhaleTeq can serve you more efficiently.

3.2 Application Form and Payment

Please fill in UDiBar <u>Application Form</u>, and send it to <u>service@whaleteq.com</u>, WhaleTeq will contact you immediately as long as the application form and payment are confirmed.

3.3 Regulatory Documents

Apart from UDiBar, we provide you ISO 13485 UDI second and third tiered management documents and software verified 3Q (IQ/OQ/PQ) documents. Please refer to <u>service@whaleteq.com</u>, WhaleTeq will contact you as soon as possible.

3.4 Applying for GS1 Prefix

Before using UDiBar, users must apply for GS1 prefix on GS1 official website <u>GS1 (gs1.org)</u>. The prefix includes country and manufacture code.



3.5 Administrator Account and Password

You will receive an email after completing <u>3.2 Application</u> <u>Form and Payment.</u> Click [Activate] to start logging in as Administrator.

Hello!	
Please click "Activate" of UDI Management 1 action is required.	to proceed and it shall lead you to the website fool. If you did not create an account, no further
Company Account ID:	WHALETEQEEE
Account ID: ADMIN	
Password: xsj4gfTC	
	Activate
Regards,	
WhaleTeq UDI Manag	ement Tool

Figure 1: Administrator Account Confirmation Letter



4 MySQL Database Installation and Setting

4.1 Open UDiBar MySQL Install File

 The file includes mysql-installer-web-community-8.0.22.0 and database form setting file, udidb_image udidb_label udidb_product_detail udidb_product_list udidb_udiprint udidb_udistock udidb_udisubmit, udidb_users. Please click mysqlinstaller-web-community-8.0.22.0 to install.



Figure 2: Click mysql-installer-web-community-8.0.22.0 installation



4.2 MySQL-installer-web-community Installation

Follow the steps below to complete installation.

(1) Click [Yes] to allow APP to change your device.

Bage Bage Countrash Countra	UB_Steeler_MySQLinstallerLauncher.exe	48 LDL(Inteler),MyGQ(Jestell 48 48 48 48 48 48 48 48 48 48 48 48
Batter Batter Batter Boundands Doundands Dounda	Account Control by you want to allow this app to make anges to your device? MySQUnstallerLauncher.exe	
Documents	rified publisher: Oracle America, Inc. le origin: Hard drive on this computer now more details	
Dourisade Movies Music		

Figure 3: Allow APP to change device

(2) Select [Custom] to begin installing the database.



Figure 4: Select Custom to install



(3) Select MySQL Server 8.0.24 x64 and MySQL Workbench 8.0.24 x64. Click [Next] to continue.



Figure 5: Select MySQL Server 8.0.24 x64 and MySQL Workbench 8.0.24 x64

(4) After confirming it is correct, click [Execute] to install.

MySQL Installer			-		\times
MySQL. Installer Adding Community	Installation The following products will be installed.				
Choosing a Setup Type Select Products	Product MySQL Server 8.0.24 MySQL Workbench 8.0.24	Status Ready to Install Ready to Install	Progress	Notes	
Installation					
Product Configuration					
Installation Complete					
	Click [Execute] to install the following pack	ages.			
		< Back	Execute	Cance	el

Figure 6: Click Execute to install



(5) After installation is finished, a green check mark will appear, and Status shown as Complete. Click [Next] to continue.



Figure 7: Complete the installation

(6) Below shows MySQL connection setting, please make sure you follow the steps as the screenshots. If Port setting has been changed, please also update PC software.

MySQL. Installer Adding Community	Product Configuration We'll now walk through a configuration wizard for each of the following products:		
hoosing a Setup Type	You can cancel at any point if you wish t products.	to leave this wizard without configuring all the	
efect Products	Product	Status	
stallation	MySQL Server 8.0.24	Ready to configure	
roduct Configuration			
stalketion Complete			
	(c :	Next > Cance	

Figure 8: MySQL connection setting (1)



• Click [Next] to complete installation.



Figure 9: MySQL connection setting (2)



Figure 10: MySQL connection setting (3)



(7) Enter MySQL root password, which is "test". Click [Next] to complete installation.

MySQL Installer		-	• ×
MySQL. Installer MySQL Server 8.0.24	Accounts and Roles Root Account Password Enter the password for the root acco	ount. Please remember to store this password in	a secure
Type and Networking Authentication Method Accounts and Roles	MySQL Root Password: Repeat Password:	••••	
Windows Service Apply Configuration	MySQL User Accounts Create MySQL user accounts for yo consists of a set of privileges.	our users and applications. Assign a role to the u	ser that
	MySQL User Name	Host User Role	Add User Edit User Delete
		< Back Next >	Cancel



MySQL Installer	- 0 ×
MySQL. Installer MySQL Server 80.24	Windows Service
Type and Networking Authentication Method	Windows Service Details Please specify a Windows Service name to be used for this MySCK Server instance. A unique name is required for each instance. Windows Service Name: MySCL80
Accounts and Roles	Start the MySQL Server at System Startup
Windows Service	
Apply Configuration	Run Windows Service as The MySGL Server meeds to run under a given user account. Based on the security requirements of your system you need to pick one of the options below.
	Standard System Account
	Recommended for most scenarios.
	O Custom User
	An existing user account can be selected for advanced scenarios.
	500
	« Back Next » Cancel

Figure 12: Set MySQL password (2)



Click [Execute] to carry out.



Figure 13: Set MySQL password (3)

Click [Finish] to complete Configuration setting.



Figure 14: Set MySQL password (4)

×

Cancel

Next 2



Click [Next] to complete installation.

Figure 15: Set MySQL password (5)

(8) Below shows MySQL Server and workbench are installed.



Figure 16: Complete MySQL setting



5 MySQL User and Schema Establishment

5.1 Establish MySQL Connection

(1) Open MySQL Workbench, click "+" next to MySQL Connections to add new connection setting.

- Hostname: 127.0.0.1
- Port: 3306, if it has been updated, please change correspondently
- Username: root
- Password: test, click [Test connection] to check if it is able to connect

	Traffic Constant Party State	Andre See Josher Andre See Josepher Seesander Selfer Andre Selfer Andre Selfer Andre Selfer	n)*** (====) terred (new de	Jahari a a anali i fa dha	
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fySQ: Carrectaile Tecefroat	Connection Name: 0	ahat			
	Correcton Aenale I	Kanagement System Prof	•		
	Connection Methods	(Sandard (107(27)		Y Method to use to correct to the ROBM	5
	Hetune	127.0.0.1	Ports (3306	Name or IP address of the server heat - and	
	Oversame	Inet		TOP IP part.	
	100 million (100 million)	Dars & Last	Over	The user's parameted. Will be requested later if it's	
	Persont			AND MET.	
	Passorth Default Scheras			The otherne to use as default scherus. Lasive	
	Personal Default Scheme			The scheme to use as default scheme. Leave Mark to adoct it later.	
	Default Scheme			The schema to use as default schema. Leave blank to adoct it later.	
	Permorett Default Scheme			The schema to and an oblight schema. Leave Mark to which it later.	
	Passorit Defail Scherer	· · · · · · · · · · · · · · · · · · ·		The scheme to use as default scheme. Leave Mark to select it later.	
	Passori Defail Scharter			The scheme to use as default scheme. Leave	

Figure 17: Set MySQL connection





(2) A connection notice will be shown on the homepage.

Figure 18: Complete MySQL connection setting

(3) Click the Connection item; a pop-up window will ask you to enter password. Enter "test" for now.

Note : You can change the password after installation has been done.



Figure 19: Enter MySQL password



5.2 Establish MySQL User

(1) Login and click [Administration], switch to [Users and Privileges], and select [Add Account].

Manufacture .	dant one		A COLUMN TO LAND		
Bondination Constraints Constrain	Les Traites	Reference of a constraint			
ninistration	Add A	count	Ball Mill House Ann		

Figure 20 : Add Account

(2) Add a user, named as UDIdb, and password UDIdb0000

The Assessment of Street	Advantation Dalas - Column Dalat	
Account units	Administrative Roles Screne Privie	yes
Login Nar	ne: U01db	to connect from different hosts.
Authentication Typ	pe: Standard	For the standard password and/or host based authentication select 'Standard'.
mit to Hosts Matchin	ng: [%	% and _ wildcards may be used
Passio	rd:	Type a password to reset it.
	Medium strength password.	
Confirm Passwo	rd:	Enter password again to confirm.
	Ciore Pantword	

Figure 21: Add User



(3) After setting account and password, switch to

 [Administrative Roles] to authorize. In Global Privileges,
 select "CREATE"," DELETE"," INSERT", "SELECT "and
 "Update". Click [APPLY] to finish user setting.

Gary1 saw Control Cont	Details for access of his and Details for access revealed the source is access to access the source of the source is access to access the source of the sour	ALTER ALTER ROUTINE CREATE
mpel opsile med op med op med med med States read states s	Ale Description Ale Description Participational des autors and the option to participation of the option to participation of the option of t	CREATE TABLESPACE CREATE TABLESPACE CREATE USER CREATE VIEW DELETE DROP EVENT EXECUTE FILE GRANT OPTION INDEX NISERT
(Instance)	The second se	LOCK TABLES PROCESS REFERENCES RELOAD REPLICATION CLIENT REPLICATION SLAVE SECT

Figure 22: Complete user setting

5.3 Establish MySQL Schema

(1) Right-click Schema area, select [Create schema]

Navigator		1		- 0 ×
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Q Filter objects				T T IN G LAWS
B sys Losd Spec Create Sci Refresh A	Sol Dana Ierra. I	Binneys Marken and ange and ange and ange and ange and ange and ange and ange ange and ange ange and ange ange and ange ange and ange	Materializes A 100 A 100 CH	Actionatic content being to installed, they to toolher to memory and post-being to the immunity and post-being to the biggite subsector being.
		Ande il Tratige		
Re-short address and and address a	Cheeric (Cheeric)		Date and	(non-see) and a
3 Aur 10		-		Andrew State

Figure 23: Create schema (1)



(2) Click [Apply] after entering username udidb, and click[Apply] again after pop-up window shows up. Click[Finish] to complete the setting.

Ny SQL Washbench				- 0 ×
Query 1	users	Administration -	Users and Privil	udidb - Schema $~\times~$
	Name:	udidb		Specify the name of the s
		Re	ename References	Refactor model, changing a
Charse	t/Collation:	Default Charset $ \smallsetminus $	Default Collatior $ \smallsetminus $	The character set and its
Adventuation Reference				
Re-signal solution	time () Anno Inno () Ten		Apply	Revert

Figure 24: Create schema (2)



Figure 25: Create schema (3)





Figure 26: Complete schema creation

(3) Click udidb in the schema, right-click [Set as Default Schema]

4	ent Con Jahan Jean Jeli Japan Jeli La Di Di Di Di Di U		- • ×
R .	Load Spatial Data Set as Default Schema Filter to This Schema Schema Inspector Table Data Import Wizard	Intelligence series Beneffe Schwarz Herbertensen, eine gene aus og underskar of stell taken, undere antelen en konken for annæn for dæret Mere taken sen Angerg af dennes here in en sogen, mere annælse mer funktion for en di denne vare in here en so Tre dennes et antelen konken menefferen after en antelen en after konken for er stell konken sog after foran for Market 7 Fre dennes et antelen konken menefferen after en antelen en after konken fore i antelen after (andere falt forande for Market 7 Fre dennes et antelen konken menefferen after en antelen en antelen en after et antelen after (andere falt forande for Market 7 Fre dennes et antelen konken forande en after en antelen en antelen en antelen et antelen after (andere falt forande for Market 7 Fre dennes et antelen konken et antelen en after en antelen et antelen	$\label{eq:response} \begin{split} & R_{\rm c} = 1 \left(\frac{1}{20} \otimes \frac{1}{2} \otimes \frac{1}{20} \right) \\ & A = 0 \text{manually can be replaced to the phase of the manually get budy for the summed (and possibles or fits brought entermatic help, begins entermatic help. \end{split}$
	Send to SQL Editor		
5	Create Schema Alter Schema	an an	tenering Store
	Drop Schema	Transpo Chargen staffet	Buston / Nech
	Search Table Data		
	Refresh All		

Figure 27: Set as Default Schema



5.4 Add udidb schema table

(1) There are eight database form setting files, including udidb_image, udidb_labe, udidb_product_detail, udidb_product_list, udidb_udiprint, udidb_udistock, udidb_udisubmit and udidb_users. All of the file setting follow the same steps as below. Take one of the file as an example. Please repeat the steps to complete all table establishment.

Aberth .				- 0 ×
New Model	Ctrl+N			0
New Query Tab	Ctrl+T		第 1 	NLANNAN ≺ ≻ <u>N</u> ¶ Argen
Open Model	Ctrl+O			Automatic context help in disabled. Use the toolbar in manually get help for the
Open SQL Script	Ctrl+Shift+O			toggle automatic help.
Open Recent		•		
Run SQL Script				
Close Connection Tab	Ctrl+Shift+F4			
Close Tab	Ctrl+₩			
Save Script	Ctrl+S			
Save Script As	Ctrl+Shift+S			
Revert to Saved				Count way in the
Exit	Alt+F4		Througe Charges assilted	Building (Target

Figure 28: Open SQL Script

Note : Please click File -> Open SQL Script at the upper left corner



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ebdb_product_list.sql	2021/2/5 下平 11:56	SQL 程度		2.KB	
ebdb_udistock.sql	2021/2/13 上午 10:11	SQL模裁		2 KB	
ebdb_udisubmit.sql	2021/4/7 下半 12:58	SQL 標館		2 KE	
ebdb_users.sql	2021/2/6 下年 03:16	SQL 模倣		2 KB	
N): ebdb_product_detail.sql		SQL Files (*.sc	¢,	~	treation brant
	saesak + uorano + UUU_steeon_iny E III e ebola_peroduct_detail.sql ebola_udistock.sql ebola_udistock.sql ebola_udistock.sql ebola_usen.sql	ares kt + uoi alo + UU()telechykys(U()ntell	aves.kt + Vorano + UUL_Station(MySQL_Initial 0 0 田田田田(Station 高橋 御台田前 開型 @ ebdb_product_letal.sql 2021/2/6 上年10.44 SQL 機能 @ ebdb_product_letal.sql 2021/2/75 下午11.15 SQL 機能 @ ebdb_udiatock.sql 2021/2/75 下午10.11 SQL 機能 @ ebdb_udiatock.sql 2021/2/75 下午10.11 SQL 機能 @ ebdb_udiatock.sql 2021/2/75 下午10.11 SQL 機能 @ ebdb_users.sql 2021/2/5 下午0.116 SQL 機能	pares X + V uor alo → UOU(Settion (MySQL)(Httell)	aves XC + Uot allo → UUU_Stabol/UNYSQU(missi) ● C 田田田田(Stabol/UNYSQU(missi) ● C 田田田(Stabol/UNYSQU(missi) ● C 田田(Stabol/UNYSQU(missi) ● C 田 (Stabol/UNYSQU(missi) ● C H (Stabol/UNYSQU(missi

(2) Select SQL Script folder, open them sequentially.

Figure 29: Select SQL Script folder

(3) Please click the thunder icon to execute Script, from udidb_image, udidb_label, udidb_product_detail, udidb_product_list, udidb_udiprint, udidb_udistock, udidb_udisubmit to udidb_users sequentially.



Figure 30: Click the thunder icon to execute Script



6 UDiBar Software Installation

(1) Unzip the software folder, and click the executable file in the folder to install.

————————————————————————————————————	tion_1.0.0.12			-	□ × √ 3	
← → 丶 ↑ 📙 > 本機 > De	sktop > WhaleTeqUDI_Station_1.0.0.12	v õ	○ 提尋 WhaleTeqUDI_Station_1.0	0.12		
★ 快速存取	名稱		修改日期	類型		大小
Documents Documents Pictures Pictures data dicomparser Outlook Temp Python User Manual OneDrive	WhaleTeqUDI_Station_1.0.0.12.exe		2021/4/22 下午 04:11	應用程式		3,898 KB
■ 王曜 ■ 30 和作 ■ Decksop ④ Documents ● Downloads ■ Movies ■ Music ■ Fictures ■ 不得証明(C)	×					

Figure 31: Click to install the executable file

(2) Click [Yes] to allow APP to change device.



Figure 32: Allow APP to change device



(3) Choose installation path. Click [Next] to finish installation.



Figure 33: Install software (1)

- E		84	WheleTextIO(Distor,100.12						- 26
11月 11月	ut	Setup	- WhaleTeg UDI Station version 1.0.0.1	12	-		×		- (
	· Deda								
	-	Select	Additional Tasks						
★ 快速市計	- 1	Whi	ch additional tasks should be performed?			6			
🕹 Dourloads	- 21								
Documents	1	Cale	of the additional tarks you would like Cebin to	carform while in	etallon W	halaTan			
St. Pictures	- 1	UDI	Station, then dick Next.	periori site e	armenta as	Instances			
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ER E	- 1	Add	itional shortcuts:						
decompanier			Create a desktop shortcut						
Outlook Temp									
Python									
User Manual									
 OneDrive 									
💷 # 19									
30 49 #	- 1								
Destop									
Documents									
Downleade									
Movies	- 3								
Music									
Pictares				back /	1x90	Car	iciei		
▲ 主接密課 (C)	J			_		1			_

Figure 34: Install software (2)



• Click [Install] to finish installing.



Figure 35: Install software (3)



Figure 36: Installation completed



7 UDiBar Cloud Database Work Flow

UDiBar- UDI generator and label management system is composed of cloud database and software. Members in the user organization will have different levels of usage restrictions according to the role permissions of different accounts. This chapter will explain the work flow of cloud database.

7.1 Company Profile

(1) Login <u>here</u> with <u>Administrator account</u> name and password in the notification mail.



Figure 37: Log in



(2) Log in and click [Company Profile].



Figure 38 : Homepage

(3) Enter company information in the upper part (Figure 39), and enter contact information of the administrator account in the lower part (Figure 40). Please note that company profile is created based on the company application form. After the information is revised, click [Submit] to update the company profile immediately.

WHALETEQ UDI Management Tool				English 🙎
Company Profile				
Company Name *	Coun	try * wan-TW		~
Company Phone Number *	Comp	any Fax Number		
Representative *	DUNS	5 number		
Company Address *				
Company Web URL				

Figure 39 : Enter company information



Contact information	
Company Account ID *	Password *
udiTest	
Contact Person Name *	Contact Job Title *
Emma	PM
Contact Person Email *	Contact Person Phone *
emma.lee@whaleteq.com	+886123456789
	Submit

Figure 40 : Enter contact information

7.2 Create Sub Account

- (1) Login with <u>Administrator account</u> name and password in the notification mail.
- (2) UDiBar provides <u>Administrator</u> and <u>Sub Account</u>. The Administrator has permissions for review and approval. The Sub Account has permissions for Add Product and PI Generation. To create a new Sub Account, click [Create Sub Account].



Figure 41 : Enter Create sub account


(3) After filling out the form, click [Submit] in the right bottom corner to create the Sub Account.

WHALETEQ UDI Management Tool					English	2
Create Sub Account						
Account ID*						
Account Name*		Acco	unt Job Title*			
Account Email*		Acco	unt Phone*			
Account Permission Create New DI Generate PI Database Search Account Active	/Download					
on				Sub	mit	

Figure 42 : Create sub account

(4) You will receive an email with your sub account ID and its password. Please click [Activate] button and log in with the account ID and password.

Hello!



Figure 43: User account activation letter



- (4) Notes for Create Sub Account
 - Options under Account Permission
 - Create New DI: Permissions to create new DI.
 To generate a properly encoded DI, it is recommended to be filled out and checked based on the product category by RA (Regulatory Affairs).
 - Create New PI: Permissions to create new PI. To generate correct UDI codes with the production date, it is recommended to be selected from the existing DI list by PE (Product Engineer).
 - Database Search/Download: Permissions to perform UDI database searches and downloads. It is recommended to be performed by PE or RA supervisor.
 - To activate the account, please set Account Active from [OFF] to [On] (Figure 42).



7.3 Add GS1 Prefix

- UDiBar follows GS1 standard, the most widely adopted standard by now. Before using UDiBar to create DIs or generate PI barcodes, users are required to get a GS1 Prefix on GS1 official site (See <u>Chapter</u> <u>3.4 Get GS1 Prefix</u>).
- (2) Login with Administrator account just created.



Figure 44: Click Add GS1 Prefix

(3) Fill in the columns with Country and Manufacturer Code obtained from GS1 and click [Submit].

WHALETEQ UDI Management Tool				
Add GS1 Prefix	Add GS1 Prefix		0	+ Add GS1 Prefix
	GS1 Country Code			
GS1 Country Co			ture Code:	
471	GS1 Manufacture Code		88	
006			90	
025			56 Submit	

Figure 45: Submit GS1 Prefix



7.4 Create Product

- (1) Login with Sub Account
- (2) After filling out the GS1 Prefix, user can start to add a product. UDiBar provides two patterns to add products: one is for medical device with Unit package count=1 and the other is for medical device with Unit package count>1.



Figure 46: Click Create Product

(3) The example below uses Infrared Ear Thermometer to show how to fill in the fields when the unit package count is 1. Please fill in each field according to the requirements. As this case is for Unit Package Count=1, so keep the option [Unit Package Count >1] unchecked. Click [Submit] when the details are completed, then configure the packages of each level. When the information is filled in, you can click [Submit], and create packages for each package.



There are two forms of establishing packages, one is [self-created], and the other by referring to the [Quick Start Template].

Duplicate Product GS1 Country Code + Company Prefix (9 Digits) 06557590 Country Of Sale US-DA BL-MDR Other Product Common Name* EraThermometer BioBitech Model Name* Version/Specification UT-400 Remark Device Description UD-DI Country of Retence Number UD-DI	
GS1 Country Code + Company Prefix (9 Digits) O06557890 Country Of Sale US-FDA EU-MDR Other Product Common Name" Brand Name/Trade Name" BioBtech Model Name" Version/Specification UT-400 Remark Device Description Unit Package Count > 1 Product Reference Number UDI-DI Quick Start Template Passe select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device Device Consumable Medical Device Consumable Medical Device Consumable Medical Device Consumable Medical Device Device Consumable Medical Device	
O05567890 County Of Sale US-FDA EU-MDR Observation Brand Name/Trade Name* Ear Thermometer BioBitech Model Name* Version/Specification UT-400	
Country Of Sale US-FDAEU-MDROther Product Common Name* Ear Thermometer BioBlacch Model Name* UT-400 Remark UT-400 Remark Device Description UT-400 UI-10 UI-	
Product Common Name* Brand Name/Trade Name* Ear Thermometer BioBtech Model Name* Version/Specification UT-400 Persion/Specification Device Description Device Description Outle Package Count > 1 Product Reference Number UDI-DI VDI-DI Quick Start Template Device 2. Software as Medical Device 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
Ear Thermometer BioBtech Model Name* Version/Specification UT-400 Persion/Specification Remark Persion/Specification Device Description Unit Package Count > 1 Product Reference Number UDI-DI Quick Start Template UDI-DI Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
Model Name* Version/Specification UT-400	
UT-400 Remark Device Description Unt Package Count > 1 Product Reference Number UDI-DI Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical Device	
Remark Device Description Divice Description Unit Package Count > 1 Product Reference Number UDI-DI Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
Device Description Unit Package Count > 1 Product Reference Number UDI-DI Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical Device	
UDI-DI UD	
Unit Package Count > 1 Product Reference Number UDI-DI Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
UDI-DI LISE you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical Device	
Product Reference Number UDI-DI Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical Device Device	1.
Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device	
Quick Start Template Please select one Quick Start Template for the preset packaging information. Else, you may click "Submit" to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical 4. Consumable Medical Device Device Device 1. <t< td=""><td></td></t<>	
Please select one Quick Start Template for the preset packaging information. Else, you may click 'Submit' to add your own packaging. 1. Active Device/Reusable Device 2. Software as Medical Device 3. Implantable/Invasive Medical Device 4. Consumable Medical Devi Device	
	e
Ear Thermometer Software as Medical Device Catheter Syringes	80 2010
Unit Level Package 😥 ** 🖉 Unit Level Package 📸 Unit Level Package 🔂	
2nd Level Package 20	
Del Luver Package 🖉 🔮 pat Luver Package 🧭	
2d Leel Palage 🥶 😅 be Leel Palage	
Cancel Add Package	

Figure 47: Create Product

(4) Self-created: directly press [Submit] after filling in the information. Pay attention to the Reference Number and the number of Unit in this package of each level.



After creating the package, click [Add package] in the lower right corner to send the data, and then you can see the new data in the Product List. At this time, you need to wait for the Administrator to review and sign off. Or if the data has not been completed, you can click [Draft], so that the data can be edited later.

					Home	Product	ltem	English	2
Add Package									
Product Common Name		BRAND NAME			Model				
ааа		BioBtech			UT-400)			
Specification									
Unit Level 🕒 Ur	nit package							(i
2nd Package 🕒 Bo	x for EU		i Box for U	JSA					
3rd Package 🔂 Ca	irton 1		00						
		Back		Add Packag	e		Dr	əft	
Unit level is Primary DI on MD or Please click ① and check your unit	unit package. Is in package and PI c	options.							

Figure 48: Add Package

(5) Quick Start Template: Four categories are included, which are "Active Device/Reusable Device", ,
"Software as Medical Device", "Implantable/Invasive Medical Devices", and "Consumable Medical Device". The following example is an Ear Thermometer, so we choose " Active Device/Reusable Device ". Pay attention to Units in Package and PI options when making packages of all levels. If you select the [Quick



Start Template] to create, the created packaging sample will be preset.



Figure 49: Click Quick Start Template "Ear Thermometer"

WHALETEQ UDI Management Tool					Item English
Add Packag	e				
Product Common Nar	ne	BRAND NAME	Model	10	
Specification		Biotech	014		
Unit Level	• Unit package	UDI Management Tool	×	_	0
2nd Package	Box for EU	Check "Units in package" and "PI options" of each packa	ige!		
3rd Package	Carton 1		Confirm		
		Back Add Pa	ackage		Draft
Unit level is Primary D Please click ① and che	on MD or unit package. ck your units in package a	nd PI options.			

Figure 50: Pop-up page to confirm "Units in package" and "PI options" of each package



(6) If the unit package count of medical device is greater than 1 (Unit package count>1), please refer to the following methods to complete the information. If [Unit package count>1], we need to create UOU DI for this product. After filling in the product information, check the option Unit package count>1, and create UOU DI.

WHALETEQ UDI Management Tool	Home Product Item English
Create Product	Duplicate Product
GS1 Country Code + Company Prefix (9 Digits) 025123456 V	
Country Of Sale US-FDA EU-MDR Other	
Product Common Name*	Brand Name/Trade Name*
aaa	BioBtech
Model Name*	Version/Specification
01-400	
Remark	
Device Description	
☑ Unit Package Count > 1	
UOU DI List	1
· · · · · · · · · · · · · · · · · · ·	
Create New UOU DI	
Product Reference Number	UDI-DI
047 🗸	(01)00065678900472

Figure 51: Create UOU DI

(7) After creating the Unit Package, please choose a reference number for the package in each level. In the Add Package step, please choose the Reference Number and Indicator of DI, and choose the PI based



on the product and the package level. The packaging section is set once this operation is done. Click [OK] to finish the configuration for a level.

WHALETEQ UDI Management Tool	Home Product Item English
Add Package	
Unit package Package Details	0
Reference Number Indicator Units in p 047 0 1 1	ackage Units in per package Total in package
Note	
Unit package	
UDI	
(01)00065678900472(11)N6(21)X20	
(00)-Serial Shipping Container Code (SSCC) -N18	(11)-Production date (YYMMDD) -N6
(02)-GTIN of contained trade items -N14	(21)-Serial number -X20
(10)-Batch or lot number -X20	
(12)-Due date (YYMMDD) -N6	
	ок

Figure 52: Fill in Unit Package information

(8) Notes for Add Product

 In [Add package] section, the Reference Number of the first level Unit Package is set on the previous page. However, starting from the following levels, if you do not choose Quick Start Template, the Reference Number of each level must be set by yourself. After all packages are built, click [Add Package] to submit this setting.



WHALETEQ UDI Management Tool		Home Pro	oduct Item English
Add Package			
Product Common Name	BRAND NAME	Model	
aaa	BioBtech	UT-400	
Specification			
Unit Level 🕒 Unit package			()
2nd Package 🕒 Box for EU	i Box for USA		
3rd Package 🕒 Carton 1	i o		
-	Back Add P	Package	Draft
* Unit level is Primary DI on MD or unit package. * Please click ① and check your units in package and PI	options.		

Figure 53: Add Package

 The product created shows in the product list after submission. There are two DIs in the table because [Unit package count>1] was checked. This step will send the details of the product to Administrator for approval. Once it is approved by the Administrator, the user can generate its PI.

		LETEQ germent Tool		Home Product Item English					
Choose	One Product to	View Informa	tion						
Keyword		Prom yyyy/用/di	d 🗐 To yyyy/用/dd					G	Search
	Product Name	Model Name	UDI-DI	UOU DI	USED PI	STATUS	Version/ Specification	Creation Date	View Details
	222	UT-400	(01)00065678900472		0	Pending		2022-07-06 13:20:04	۲
	test	FR1MN1	(01)04718868880237		0	Pending	01	2022-07-04 13:54:47	۲
	FR	FR1MN1	(01)047188888880053		0	Pending	01	2022-07-01 14:48:12	۲
	aa	ET 500	(01)00251234560482		0	Pending		2022-06-30 16:15:46	۲
	"Testing Kit"	ET 500	(01)00251234560246		0	Pending		2022-06-24 16:50:25	۲
	DNA testing kit	VK-DNA 302	(01)00251234560222		0	Draft		2022-06-17 17:49:07	۲
D	DNA testing kit	TK-DNA 356	(01)00251234560215		0	Pending		2022-06-17 17:47:35	۲
	TEST	TEST-111	(01)04718888880022	(01)04718888880015	0	Approved		2022-06-17 14:42:32	۲

Figure 54: Product List



7.5 Pending Approval Product List

- (1) Login with Administrator account
- (2) Administrator can review the details sent by Sub Account from Add Product step. (e.g., amount, reference number and level setup). The product can then be approved as long as the details are verified.



Figure 55: Click Pending Approval Product List

(3) Here is an example of Ear Thermometer with Unit package count=1. Click [Pending Approval Product List] on home page to view the list of products sent by user that are pending approval. The Administrator can select a product to proceed, and click [View Detail]

	TEQ nt Tool	Home Compa	ny Product Pending Appr	oval Account English	2
Pending Approval Product	List				
Product Name	Model Name	UDI-DI	Version/ Specification	Creation Date	View Details
202	UT-400	(01)00065678900472		2022-07-06 13:20:04	۲
Ear Thermometer	88T 140	(01)00065678900151		2022-05-09 15:18:55	۲
FR	FR1MN1	(01)04718888880053	01	2022-07-01 14:48:12	۲
aa	ET 500	(01)00251234560482		2022-06-30 16:15:46	۲
"Testing Kit"	ET 500	(01)00251234560246		2022+06+24 16:50:25	۲
DNA testing kit	TK-DNA 356"	(01)00251234560215		2022-06-17 17:47:35	۲

Figure 56: Click to view detailed information



(4) Click [Approve] after the details of each packaging level are verified. Otherwise, click [Reject] to return this product to user for further modification.

Model UT-400
Model UT-400
θ
Δηστογο

Figure 57: Product information review

7.6 Product List

- (1) Login with Administrator account
- (2) Click [Product List] to view all the products created by the Sub Account. Both the approved and pending approval ones can be searched in the Product List.



Figure 58: Click Product List



(3) Here is an example for Ear Thermometer:

								QMS English	
選擇單-	一產品 檢視資訊								
關鍵字		從 yyyy/月/dd	☑ 至 уууу/月/	'dd 📼					Q 投募 ▲ 孫出
	Product Name	Model Name	UDI-DI	UOU DI	USED PI	STATUS	Version/ Specification	Creation Date	View Details
	Hypodermic needle	ORP191	(01)04714799530148	(01)04714799530131	0	Approved		2020-11-03 11:19:51	۲
D	Ear Thermometer	MQ001	(01)04714799530100		3	Approved		2020-11-03 11:10:52	۲
	Ear Thermometer_2	ET001	(01)04714799530070		0	Rejected		2020-09-23 15:08:41	۲
	Syringes	w323	(01)04714799530049	(01)04714799530032	0	Approved		2020-09-23 14:50:07	۲

Figure 59: Product List

- Product Name: The name of the product just created, Ear Thermometer in the example
- Model name: The model of the product, MQ001 in the example
- UDI DI: Used for identifying manufacturer name, product model, etc., which is (01)04714799530117 in the example. In this DI, (01) is the Global Trade Item Number AI, 0 is the minimum indicator of the package, 471479953 is the manufacturer code assigned by GS1, 011 is the custom reference number, and 7 is the check digit calculated by an algorithm.
- UOU DI: If Unit package count>1, it will be shown on the list
- Used PI: Calculates the number of PIs that were used. In the example, 3 indicates that the product has used 3 PIs.



- STATUS: The status of the product. APPROVED in the example means the Administrator has reviewed and approved it. REJECT means the Administrator has reviewed and rejected it.
 SUBMIT means the Administrator has not reviewed it
- Version/Specification: The version and specifications of the medical device
- Date: The creation time of the product, which is 2020-11-03 11:10:52 in the example
- View Detail: Click to view the detailed product information



7.7 Customer Service Button

 This function is available both logging to Administrator account and Sub Account. It can help you be familiar with this system faster. You can also use this button to get help when you have any questions.

WHALETEQ UDI Management Tool	н	ome Company Proc	duct Pending Approval	Account English
	-			
Company Profile	Pending Approval Product List NEW:	39 Create Sub Account	0 53 Product List	53 Add G51 Prefix FAQ Tutorial Video
Tel:+886-2-2517-6255 Emailster Copyright © WHALETEQ CO., LTD A	vice⊜whaleteq.com Address: 8F, 1 Il Rights Reserved. Terms & Condition:	4o. 125, Songjiang Rd., Zhongshan I i Privacy	Dist., Taipei City 104474, Taiwan	f to to

Figure 60: Customer Service Button

- FAQ : Click to jump to the FAQ of UDI Platform page
- Tutorial Video : Click to jump to the Tutorial Video page
- Contact Us : Click to open the mail function directly, and inform us of your problem via Outlook mail



8 UDiBar Software Work Flow

UDiBar- UDI generator and label management system is composed of cloud database and software. Members in the user organization will have different levels of usage restrictions according to the role permissions of different accounts. This chapter will explain the work flow of software.

8.1 Setting

8.1.1 Database Setting

(1) Click Setting button, select [Database] and press [Cloud] to enter setting database page.

Cloud Database Cloud Database Backup Tag Print Restore ERP Integration Cenerate Label Editor	ð ×	- 6				5.4)	WhaleTeq UDiBar (Ver. 2.22
Cloud Database Backup Tag Print Restore ERP Integration Cenerate Label Editor	∋	国 ۞ ④ 日					_
Image: Second secon		Database	📥 Cloud				
Restore Generate Label Editor	,	Tag Print	👌 Backup				&
Q Generate Label Editor Image: Constraint of the second s	tion	ERP Integration	Restore				
Generate Label Editor Image: Comparison of the second se			0704				
Generate Label Editor							Q
			Label Editor		Generate		
							5997
		<u>renen</u>		Turn		「「「」	
		u_u_u_		6		نگ	
Inquiry Barcode Check Inventory MGT		Inventory MGT		Barcode Check		Inquiry	\sim
							้ไปไ
Copyright@WhaleTi	aleTeg	Copyright@WhaleT					

Figure 61: Click Setting button on the homepage



(2) The settings of the database server IP, communication port, company account password, and user account password will appear on the page. If you have updated your data before logging in, you need to click [Update] to update the database settings. When all settings are completed, press the [Close] button to complete the database setting operation.

Whale Teg UDiBar (Ver. 2.22.5.4)			= © → ×
	<u> </u>	abase Cloud Account	
Q	Local DB Server IP F 192.168.103.31	Port ● 3306 • Co	onnect
juu;	Company Accout ID on Cloud F	Password	pdate
ŵ	Username F Asdfgh	Password	
ŵ	Inquiry	Close Barcode Check	Inventory MGT
			Copyright@WhaleTeq

Figure 62: Update database button

Note: The database host IP is connected to the server in

the user organization

8.1.2 Printer Setting

Click Setting button, select [Tag Print] and press
 [Printer] to enter setting printer page.





Figure 63: Printer button

(2) Pop-up page of printer settings appear, and click the option field of the printer (shown by the red box in the figure below), and select the printer as the link setting.

WhaleTeg UDiBar (Ver. 2.22.5.4)						٩	3 🖾 🕀 Ξ	× >
			P	rinter Setting				
Q		Printer	Top Margin		Right Margin	Bottom M Asso	Argox	
<u>[!!!!]</u>		0 Label Width 10.0	0 Label Height 6.0	dot Unit ● cm ○ inch	0 Printer Resolutio • 203	0 🗩	DOMINO ZEBRA Windows	
Â		Label Sampling (Check		Label Duplicate	1		
ல	Inquir	Load Print Pack	age	Close Barcode Check	Print	as Image	entory MGT	
							Copyright@WhaleT	eq

Figure 64: Select a printer

Note: Supports format of Windows Driver, the settings need to be synchronized with your computer settings Click Windows Settings \rightarrow Printers and Scanning \rightarrow Select Printer \rightarrow Manage \rightarrow Print Preferences \rightarrow Page Setup



(3) Set paper size, printer resolution (shown by the orange box in figure 65); for barcode check settings (shown by the orange box in figure 65), you can set the sampling rule by yourself (shown by the blue box in figure 65), and determine the number of copies to be printed (shown by the red box in figure 65).

For example: If we key-in 10, it means that when the printer is printing, every 10 barcodes will be inspected once; if users are not doing barcode check, the number will be set to 0.

(4) After all settings are completed, close the window to complete printer setting.



Figure 65: Printer settings



8.1.3 ERP Integration

(1) Click Setting button, select [ERP Integration] to enter the page.



Figure 66: ERP Integration button

(2) A pop-up window will show up to set up ERP integration.

leTeq UDiBar (Ver. 2.22.5.4)					E 🛱 🏶
		<u></u>	ERP Integration		
Q		CSV Folder			Clear
į		Mapping Table Field (01)DI	Index in CSV Remark	Î	
	<u>آ</u>	Product/Model Package Count	0 0 0		
		(10)Batch or Lot Number	0 Close	>	
Â	Inquir	У	Barcode Check		Inventory MGT

Figure 67: ERP setup options



(3) Export ERP data as CSV file to a new folder. Open UDiBar and import the file. Fill in the information fields to correspondent table.

WhaleTeq UDiBar (Ver. 2.	
	建筑 间和元 ×
Q	C Online Services Whate Treg Whate Treg Clear Clear
jiiii)	ja ko zh-hans zh-hant
Â	Windows Mail Windows Mail Windows Mail Windows Media Player Windows Nteila Player Windows Photo Viewer Windows Photo Viewer Windows Photo Viewer
俞	Inquiry BIR BIR Inventory MGT
	Copyright@WhaleTec

Figure 68: Import csv. file

(4) Open it after selecting the corresponding folder.UDiBar will display the ERP data.



Figure 69: Opening imported file



(5) To close ERP integration, repeat step (1) to open the ERP integration setting page, click [Clear] to close the window.

		2] @ ∋)
<u> </u>	01/00005678900267(11)220523(21)M822052305.cw (5/77/2022-124 PM) ABC: TWS20 - Unit package ERD Integration			
Q	CVTolder Clear]		
[!!!!]	Field Index in CSV Remark (01)DI 1 Product/Model 0			
Â	Count 0 (10/Batch or Lot Number 0			
ណ៍				

Figure 70: Close ERP integration

8.2 Label Generation

(1) Click [Generate] or the computer symbol on the left side.



Figure 71: Click Generate



(2) Enter product list page, select the product you want to create a label.

eTeq UDiBar (Ver. 2.22	2.5.4)			E 🕸 🌐	5
	Choose N	todel Select Package	Fill & Print	Finish	
0	Product	Model	UDI-DI	UOU DI	í
	Testing Kit	BBT 100	(01)00065678900038	(01)00065678900021	
	WhaleMed	WM-100	(01)00065678900069	(01)00065678900021	
	Medical	MD-80	(01)00065678900113		
คิ	Medical Device	MD-90	(01)00065678900144	(01)00065678900137	
	Testing Kit	ET 500	(01)00065678900236	(01)00065678900021	
\sim	ABC	TW520	(01)00065678900267		
- N	1100000	1.11.1.00	(01)00005070000004	0100005170000000	

Figure 72: Enter product page

(3) After clicking the product, it will automatically enter the package selection page, and select the product package layer that has been created and to be printed.

WhaleTeq UDiBar (Ver.	2.22.5.4)					2	ŝ	- •	⇒ >
		Choose Model	Select Package	Fill & Print	- Finis	sh			
	Product		Model						
Q	Testing Kit		BBT 100						
[!!!!]	⊫– <mark>Kit</mark> – B	lox							
Â									
仚									

Figure 73: Select package



(4) Enter printing page, fill in PI information, and click Submit & Print.

WhateTeq UDillar (W	w. 2225.4)				
	Choose Moo	lel 😭 Select Packa	ige 🔒 Fill & Prin	. <u>P</u>	Finish
	Product	Model			Package Level // Name
Q	Testing Kit	BBT 100)		Box
	Create Code				*
ົາແມ່	Production Date	Expirat	tion Date		
57	Saturday, May	Sat	urday, May	y ~	
â	Batch or Lot Number	Serial I	(17)230705 Number		
	ABC1234	1 : XX	X 0000	01 1	
\wedge	(10)ABC1234		(21)XXX00000)1	
َلْمَا	UDI (01)00251234560017	(11)220705(17)23070	05(10)ABC1234(21)XO	0000001	Submit & Print
					Complete Children Ten

Figure 74: Submit and Print

Note: PI items are established in the Cloud database, and the actual numbers are filled in as figure 74 shown.

(5) Users can choose different formats according to the specifications to be printed, including 1D and 2D codes, or labels that are already approved. In addition, exporting CSV file is also available.

				E 🕸 🌐 🗩
	, D*	Choose Model 👩 Select Package	🖨 Fill & Print 🏳	Finish
	Product	Model		Package Level // Name
Q	Testing Kit	BBT 100		Bax
[!!!!]	UDI Select Label Type	(01)00251234560017(11)220	705(17)230705(10)ABC1234	(21)XXX0000001
â			csv	
ស	Default Barcoc	le Default DataMatrix	CSV	Italy

Figure 75: Select a print format





(6) Label printing process is shown in figure 76:



Note: If barcode check is selected, please refer to <u>8.1.2 Printer</u> <u>Setting</u> for the sampling check setting. During printing, you are required to stop it and use barcode scanner to check the printed labels. After passing barcode check, printing will continue. Click [Abort], the printer will immediately stop printing labels.

(7) When the barcode printing is completed, the record will be displayed in the product barcode list.

				四 ۞ ④
	Choose Model	ckage Fill & Prin		inish •
Product	Model	Package Le	vel // Name	
Testing Kit	BBT 100	Box		
UDI DI	UDI	PI	Count	Creation Date
(01)00251234560	017 (11)220705(17)230705((10)ABC1234(21)XX	1	2022/7/5 下午 05:55:00

Figure 77: Printed barcode list



8.3 Label Editing

(1) Click [Label Editor] or the barcode symbol on the left side.



Figure 78: Click Label Editor

(2) The page for label editing is shown in figure 79. The left side of figure 79 is the product packaging layer, and the right side is the label column.



Figure 79: Product packaging and label column



(3) The right side is the default label of 1D and 2D label that have been generated.



Figure 80: Adding new label and duplication

Note: Right-click on the blank space of label column and select [New] to add a new label, [Paste] to copy one.

(4) The administrator logs in to the ADMIN account, clicks the edited label in the label column, and clicks the left mouse button to authorize or preview the label.



Figure 81: Authorize or preview labels



(5) The user logs in to the user account, and clicks the left mouse button on the label column to choose to edit, copy, rename, delete or preview the label.

whatered Obligar (keyword Q	E ۞ ⊕ Э
	Default Label(2) Testing Kit : BBT 100 - Kit Box - WhaleMed : WM-100 - Box for EU	
	← Medical : MD-80 - Unit Package(1) ← Box for EU ← Carton 1 ← Box for USA	Edit Copy
	Carton 2 - Medical Device : MD-90 - Unit Package - Box for EU - Testing Kit : ET 500 - Unit Package	
ம		.∞ Copyright@WhaleTeg

Figure 82: Label editing and other functions

(6) If the user logs in the user account and clicks the label editor, the edit window will pop up. The label can be edited, and the base image can also be imported.



Figure 83: Label editing and base image importing



(7) Red text on the label name indicates that the label has been authorized and can be printed; black indicates an unauthorized label; gray one indicates that the label has been sealed and cannot be used again.

	keyword ©	
ਦੇ ਵਿੱ ਪ	Default Label(2) Testing Kit : BBT 100 - Kit Box WhaleMed : WM-100 - Box for EU	Germany
) A		Maria Maria Maria sunr Maria Son Anto Son Maria Son Maria Son Maria
ស	O-Testing Kit : ET 500 - Unit Package	Italy
		Japan⇔

Figure 84: Different levels of label authorization

8.4 Barcode Check

(1) Click [Barcode Check] or the barcode symbol.



Figure85: Click Barcode Check



(2) After entering the page, connect the scanner to the computer, and use it to verify the labels. If PASSED appears after scanning the code, it means that the label has passed the test and will be saved to database.

WhaleTeq UDiBar (V	w. 2.22.5.4)	- ° × 日 🕸 🌐 Э
<u> </u>	Please aim the scanner at the barcode !	
Q	G	PASSED
(1111) (1111)		
â	رئ	
ណ៍	Product Number	
		Copyright@WhaleTeq

Figure 86: Barcode check passed

(3) If FAILED appears, it means that the label is not in the database; or the label is defective during printing.



Figure 87: Barcode check failed



8.5 Inquiry

WhaleTeq UDiBar (V	nt, 2, 2, 2, 5, 4)				고 · · · · · · · · · · · · · · · · · · ·
Q		Generate		Label Editor	
[!!!!]					
â					[미[<u>미]</u> [미[<u>미]</u> [미[<u>미]</u>
ណ៍	Inquiry		Barcode Check		Inventory MGT
					Copyright@WhaleTeq

(1) Click [Inquiry] or the magnifier symbol.

Figure 88: Click Inquiry

(2) Enter the list, only the first 100 data in the database will be displayed. You can use keywords or dates to query product information, or directly click on the product on the screen to obtain barcode details.

Select	Select 0		100		Print @
Sel. All	Product	Model	Package	UDI DI	UDI PI
D	Testing Kit	887 100	Box	(01)00251234560017	(11)220705(17)230705(10)ABC1234(21)X0X000
	Medical Device	MD-90	Box for EU	(01)10065678900165	(11)220705(17)230705(10)ABC1234
	Testing Kit	BBT 100	Box	(01)00251234560017	(11)220615(17)230615(10)ABC1234(21)X0X000
	Testing Kit	B8T 100	Bcox	(01)00251234560017	(11)220615(17)230615(10)A8C1234(21)X00(000
	MAYMED	MM 100	Unit Package	(01)00065678900304	(11)220606(17)230606(10)A8C1234
	MAYMED	MM 100	Unit Package	(01)00065678900304	(11)220530(17)230530(10)ABC1234
	MAYMED	MM 100	add package	(01)00065678900342	(11)220530(17)230530(10)ABC1234

Figure 89: Query product information



(3) Check the box on the left side of the product list and click [Print] to print the selected barcode again.

Select	0		100		Print G
Sel. All	Product	Model	Package	UDI DI	UDI PI
	Testing Kit	887 100	Box	(01)00251234560017	(11)220705(17)230705(10)A8C1234(21)X000
D	Medical Device	MD-90	Box for EU	(01)10065678900165	(11)220705(17)230705(10)ABC1234
	Testing Kit	88T 100	Box	(01)00251234560017	(11)220615(17)230615(10)A8C1234(21)X0X00
	Testing Kit	BBT 100	Box	(01)00251234560017	(11)220615(17)230615(10)ABC1234(21)X0X00
0	MAYMED	MM 100	Unit Package	(01)00065678900304	(11)220606(17)230606(10)ABC1234
	MAYMED	MM 100	Unit Package	(01)00065678900304	(11)220530(17)230530(10)A8C1234
	MAYMED	MM 100	add package	(01)00065678900342	(11)220530(17)230530(10)ABC1234

Figure 90: Print barcode again

 (4) After entering the page, you will get product detailed information, including: product number, product name, product model, product packaging level, UDI DI, UDI PI, barcode production time and PI table.



Figure 91: View product details



(5) At the same time, you can also verify barcode on this page. Point the scanner at the printed barcode for verification. If there is a green thumb up, it means that the barcode meets the standard (Figure 91); if a red thumb appears down, it means the barcode does not meet the standard (Figure 92).

S WhateTeq UDiBar (Ve	r. 2.225.4)	(- ° <u>×</u> ⊇ @ ⊕ ⊇
	(01)00251234560017(11)220	705(17)230705(10)ABC1234(21)X00000001	
Q ())))	Information Print History Name Testing IOI Model BBT 100 Package Box UDI DI	Creator: Audigh	(01)00251234560017 (11)220705 (17)230705 (10)ABC1234 (21)XXX000001
ش	(01)0025123456017 Date 2022/7/5 下午 05:55:00 P1 Table Production Date 220705 Expiration Date 230705 Batch or Lot ABC1234		
UU		Ц	Co yright@WhaleTeq

Figure 92: Scan barcode to verify



8.6 Inventory Management

(1) Click [Inventory MGT] or the warehouse symbol.

Note: MGT stands for Management.



Figure 93: Click Inventory MGT

8.6.1 List

 There are three functions included: list, stock in and stock out. The following is a list of products that are already in stock. You can click on the product and check its status.



Figure 94: View Inventory List



(2) After entering the page, you will see the status of the product in terms of days. Stock-in is indicated in green; Stock-out is indicated in red. Then click on a date to see all the details of that day.

묘			C (\$ (\$]
	udDemo +6		2021/08/06
Q	udDemo	-1	2021/08/06
(!!!!) (
â			
仚			
			Copyright@WhaleTeq



			日 🕸 🌐 Э
	List Stock In Stock Out		
	UDIPI	2.2	約開
~	(11)210806(17)210806(21)ABC000001	1	17:30:04
Q	(11)210806(17)210806(21)ABC000002	1	17:30:09
	(11)210806(17)210806(21)ABC000003	1	17:30:14
Sung	(11)210806(17)210806(21)ABC000004	1	17:33:22
J	(11)210806(17)210806(21)ABC000005	1	17:33:27
	(11)210806(17)230806(21)ABC000001	1	18:17:53
ULL			
~			
1പ്			
00			
			Copyright@WhaleTeg





8.6.2 Stock In

(1) Click the [List] above, switch it to [Stock in] mode, and connect the barcode scanner to the computer.

WhaleTeq UDiBar (V	ier, 222.5.4)		D	- °_× ⊕ ∋
<u> </u>	List Stock In Stoc	ck Out		
Q	1 Urfe Wetch&P O3 : Unit packing 2 非显示 : 第一篇	• 6 5	(01)04711234560043 (01)04711234560074	
(!!!!))	3 Electric Surgical Table : Unit pack	apa 3	(01)04731234580104	
Â				
ស				
			Copyright	@WhaleTeq

Figure 97: Inventory List

WhateTeq UDiBar (Ve	x 2.225.4		d	•	°_× ∋
 	List Stock In Stock Ou Please aim the scanner at the barcode !	Name			
Q	ſī	Model Package			
(!!!!) (UDI DI Date			
â	L	Pt Table			
ស្	Product Number				
			Copyrig	ht@Wha	peTel

Figure 98: Stock in


(2) Aim the barcode scanner at the barcode of the product to be put in stock, and the barcode scanned will appear on the screen. When the stock-in button appears on the screen, click it with the left mouse button, and it is successfully completed.

WhateTeq UDiBar (Vi	w. 2.225.4)		27	0	•	, <u>×</u>
	List Stock In Stock Ou Please aim the scanner at the barcode !	Name				
_ م	۳ <u></u> ۲	Model Package				
(!!!!!)		UDI DI				
â	Stock in -	Pt Table				
ស្	Product Number	00008				
			Co	ovriah	nowh:	leTea

Figure 99: Scan barcode to stock in



8.6.3 Stock out

(1) Click the [List] above, switch it to [Stock out] mode, and connect the barcode scanner to the computer.

WhateTeq UDiBar (V	fer, 2.22.5.4)			ロ 🕸 🌐 乏	×]
	List	Stock In Stock Out	Inventory		1
Q	1 2	Ufe Watch&PCB:Unit package 耳冠地:更一面	6 5	(01;04711234590043 (01;04711234590074	
[!!!!]		Electric Surgical Table : Unit package	3	(01)04711234560104	
â					
ᡬ					
				Copyright@WhaleTec	4

Figure 100: Switch to Inventory List page

WhateTeqUDiBar (Ve	n. 2.22.5.40		27	0	•	•_× ∋
_	List Stock In Stock Ou	ıt				_
	Please aim the scanner at the barcode !	Name				
Q	Too	Package				
[!!!!]		UDI DI Date				
â	<u></u>	PI Table				-
ណ៍	Product Number					
			Сор	yright	@Wha	leTeq

Figure 101: Stock out



(2) Aim the barcode scanner at the barcode of the product to be stocked out, and the barcode scanned will appear on the screen. When the stock-out button appears on the screen, click it with the left mouse button, and it is successfully completed.

WhateTeqUDiBar (Ve	w. 2.225.4)		27	0	- ())	° _×
	List Stock In Stock Ou	nt Name				
Q	۲ <u></u> ۲	Model Package				
()!!!!)		UDI DI Date				
Â	Stock out⊌	PI Table				
ណ៍	Product Number	0008				
				pyright	@Wha	

Figure 102: Scan barcode to stock out

8.7 Language Setting

(1) Click the earth symbol in the upper right corner of the homepage. Select the language you want to use; the system will restart and change to the language of your choice. Currently, the system provides three languages: English, Traditional Chinese and Simplified Chinese.



WhaleTeq UDiBar (V	er. 2.22.5.4)				- ° × ♪ ⊕ → ✓ English
					繁體中文 简体中文
Q		Generate		Label Editor	
[!!!!]					
Â					回 四 四 四 四 四
ស	Inquiry		Barcode Check		Inventory MGT
	-				Copyright@WhaleTeq

Figure 103: Language setting

8.8 Logout

(1) Click the logout symbol in the upper right corner of the homepage, and it will automatically log out and close.



Figure 104: Logout



8.9 Return to Homepage

(1) Wherever page you are in, just click the symbol of the house on the left to go back to the homepage.



Figure 105: Return to homepage



9 Contact Information

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