

Registration Notification

Reference Number: JH-ERA-MDR-21287V00

Effective Period: 2021.09.17-2024.05.26

This Notification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is notice that, According to In Vitro Diagnostic Medical Device Regulation (EU) 2017/746, we accepts the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Biobase Bioindustry(Shandong) Co.,Ltd.

Address: NO.9 Gangxing Road , High-Tech Zone ,Jinan City , Shandong Province, China

The Manufacturer declares that the IVD Device complies with the all essential requirements of In Vitro Diagnostic Medical Device Regulation (EU) 2017/746.

According to In Vitro Diagnostic Medical Device Regulation (EU) 2017/746, the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's In Vitro Diagnostic Medical Devices and has allocated registration numbers shown in:

Semi-auto Chemistry Analyzer, UMDN code: 21-01

Registration Number: DE/CA20/01-IVD-Luxuslebenswelt-339/21

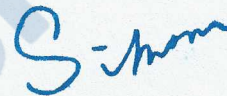
Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

Luxus Lebenswelt GmbH

Kochstr. 1, 47877, Willich, Germany
info.m@luxuslw.de

For and on behalf of

 **LUXUS LEBENSWELT GMBH**
MEDICAL-AMAZON Kochstr.1, 47877 Willich, Germany



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Only used for EU Representative Agreements

Declaration of Conformity

Manufacturer: Biobase Bioindustry(Shandong) Co.,Ltd
NO.9 Gangxing Road, High-Tech Zone, Jinan City ,
Shandong Province, China

SRN: CN-MF-000025015
whose single Luxus Lebenswelt GmbH
Authorized EU- Kochstr.1, 47877, Willich, Germany
Representative: : SRN:DE-AR-000005110
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: Semi-auto Chemistry Analyzer
BIOBASE-Silver

Basic UDI-DI: 6936895BS00224

Classification (IVDR, Annex VIII): Class A, Rule 5.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Applied standards, common specification, guidance:

ISO 14971:2019, EN ISO 18113-1:2011, EN 13612:2002/AC:2002, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, IEC 61010-1:2010+AMD1:2016 CSV, IEC 61326-1:2012, IEC 61326-2-6: 2012.

Signature: *Xiumeng Zhang*

Date: *2023.02.27*

Title: *QM*

Position: *Jinan*



Semi-auto Chemistry Analyzer

BIOBASE-Silver



Features:

- ①. 7.0 inch LCD touch screen, graphical interface is easy to use.
- ②. Large memory space, can store 300 test items, 20,000 test results.
- ③. Built-in thermal printer to print measurement results and flag abnormal results.
- ④. Incubator intelligent temperature control, room temperature, 25.0°C, 30.0°C, 37.0°C four temperature options.

Parameters:

Model	BIOBASE-Silver
Sample Type	Serum, Plasma, Urine, Cerebrospinal fluid, etc
Analytical Method	End point method, Fixed time method (two-point method), Dynamic method (rate method)
Incubating Positions	20 incubating positions
Incubator Temperature	R.T. 25°C, 30°C, 37°C, four temperature options
Cuvette	Flow through a direct-reading cuvette
Wavelength	Wavelength 340/405/450/510/546/578/630nm, 2 more open filter positions
Wavelength Accuracy	±2nm
Screen	7.0 inch LCD touch screen
Language	English, French, Spanish, other languages can be customized
Printer	Built-in thermal printer
Interface	RS-232, USB
Consumption	150VA
Power Supply	AC110/220V±10%, 60/50Hz
External Size(W*D*H)	400*410*190mm
Packing Size(W*D*H)	520*490*330mm
Net Weight	9kg
Gross Weight	12kg