

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No.**CE 748092**

Issued To:

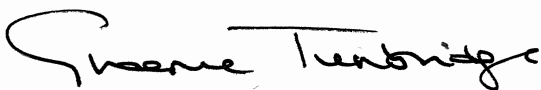
**Ningbo Co-healthy
Biotechnology Co., Ltd
No. 8, Xinheng Six Road
Cicheng Private Industrial Park
Jiangbei District, Ningbo City
China**

In respect of:

Design and manufacture of blood glucose monitoring systems for self-testing, including meters and test strips.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-18**Date: **2022-03-18**Expiry Date: **2025-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 748092

Issued To:

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Device code	Device name	Intended purpose per IFU
Annex II List B		
IVD 0309	Blood Glucose Meter (KH-100) Blood Glucose Test Strip (KH-100)	Devices for measuring glucose in blood samples. For self testing and for testing at health care centres and small-sized clinics.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Issued To: **Ningbo Co-healthy
Biotechnology Co., Ltd
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Cicheng Private Industrial Park
Jiangbei District, Ningbo City
China**

Subcontractor:

Service(s) supplied

Lotus NL B.V.
Koningin Julianaplein 10
le Verd
2595AA
The Hague
Netherlands

EU Representative

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 748092**
Date: **2022-03-18**
Issued To: **Ningbo Co-healthy
Biotechnology Co., Ltd
No. 8, Xinheng Six Road
Cicheng Private Industrial Park
Jiangbei District, Ningbo City
China**

Date	Reference Number	Action
Current	3422156	Issued.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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