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 665104**

Issued To: **IBL International GmbH**
Flughafenstrasse 52A
22335 Hamburg
Germany

In respect of:

Design, manufacture of in vitro diagnostic assays for the newborn screening of phenylketonuria (PKU) using enzymatic assays.

Entwicklung und Herstellung von In-vitro diagnostischen Test Kits für Neugeborenen Screening auf Phenylketonurie (PKU) mit enzymatischen Testsystem.

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: **2017-04-19** Date: **2022-03-28** 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.

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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Supplementary Information to CE 665104

Issued To:

IBL International GmbH
Flughafenstrasse 52A
22335 Hamburg
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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0304	Phenylalanine (PKU) neonatal Screening Assay (480 tests) (RE80015)	Enzymatic Assay for the in-vitro-diagnostic quantitative determination of L-Phenylalanine in human newborn blood spots. For neonatal screening on Phenylketonuria.
IVD 0304	Phenylalanine (PKU) neonatal Screening Assay (2400 tests) (RE80019)	

First Issued: **2017-04-19** Date: **2022-03-28** Expiry Date: **2025-05-26**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 665104**
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Date	Reference Number	Action
19 April 2017	8648877	First issue. Transfer from another Notified Body.
15 June 2017	8744996	Certificate renewal.
23 January 2019	8649216	Traceable to NB 0086.
09 December 2019	3106199	Scope reduction Removal of Immunolab GmbH Sub-contractor Addition of device table
Current	3599086	Re-Issued- Certificate Renewal