

# 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-04-19**

Date: **2019-12-09**

Expiry Date: **2022-07-01**

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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 665104

Issued To: **IBL International GmbH**  
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**Germany**

Number	Device Name	Intended purpose per IFU
<b>Annex II List B</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)	

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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.

# EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 665104**  
 Date: **2019-12-09**  
 Issued To: **IBL International GmbH  
 Flughafenstrasse 52A  
 22335 Hamburg  
 Germany**

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.
Current	3106199	Scope reduction Removal of Immunolab GmbH Sub-contractor Addition of device table

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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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