

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

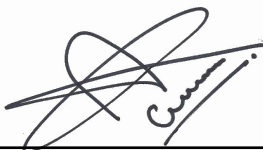
In respect of:

Design, manufacture of indirect immunoassay kits for Toxoplasmosis, Cytomegalovirus and Rubella infections. Design, manufacture of in vitro diagnostic assays for the newborn screening of phenylketonuria (PKU) using enzymatic assays.

Entwicklung und Herstellung von indirekten Immundiagnostik Kits für Toxoplasmose, Cytomegalovirus und Rubella Infektionen. 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):



Albert Roossien, Regulatory Lead

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

Date: **2019-01-23**

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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List of Significant Subcontractors

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

Certificate No: **CE 665104**
Date: **2019-01-23**
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Germany

Subcontractor:	Service(s) supplied
Immunolab GmbH Otto-Hahn-Straße 16 Kassel 34123 Germany	Design Development Manufacture

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 665104**
 Date: **2019-01-23**
 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.
Current	8649216	Traceable to NB 0086.

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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

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