EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 724873 R000

Manufacturer: IBL International GmbH

Address:
Flughafenstrasse 52A
22335 Hamburg
Germany

Single Registration Number: DE-MF-000015709

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-01-27**

Current Issue Date: **2023-11-14**

Starting Validity Date: **2023-11-14**

Expiry Date: **2026-01-26**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0102- Immunochemistry (immunology) IVP 3007- In vitro diagnostic devices which require knowledge regarding immunoassays	Immunochemistry/radioimmunoassay devices intended to be used to measure hormones as an aid in the diagnosis and treatment of adrenal disorders or aid in diagnosis of adrenal or neuroendocrine tumours.

Class B devices	Intended purpose
IVR 0608- Devices intended to be used for screening, determination or monitoring of physiological markers	Immunoassay devices intended to be used for screening, determination or monitoring of physiological markers.
IVR 0602- Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	Immunoassay/radioimmunoassay devices intended to be used for screening, determination or monitoring of autoantibodies for autoimmune diseases.
IVR 0603- Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	Immunoassay device intended to be used for the measurement of histamine as an aid in the diagnosis of allergic disorders.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-01-27	3151011	First Issue
2022-06-13	3636791	Supplemented - Addition of Class B device category IVR 0602 and Class C generic device group W0102/IVP 3007 and extension of scope for Class B device category IVR 0608. Amended - Addition of manufacturer SRN
Current	30028096	Supplemented- Addition of Class B device category IVR 0603 and extension of scope for Class C generic device group W0102/IVP 3007.

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