

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that: **IBL International GmbH**
Flughafenstrasse 52A
22335 Hamburg
Germany

DUNS Number: 31-269-4785

Holds certificate No: **MDSAP 665121**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1-SOR 98/282; Japan – MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

The design, development, manufacture and distribution of in vitro diagnostic test kits and reagents in the field of endocrinology, cancer diagnostic, hypertension, gastric diseases, diabetes, thyroid function, bone and mineral metabolism, neurodegenerative diseases, immunology, apoptosis, autoimmune diseases, infectious diseases, new born screening, allergy and food intolerance.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2017-11-17

Effective Date: 2018-11-01

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