By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

IBL International GmbH
Flughafenstrasse 52A
22335 Hamburg
Germany

Facility ID Number: F000214

Holds Certificate No: **MDSAP 665121**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-11-17 Effective Date: 2023-07-02 Expiry Date: 2026-07-01

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 665121**

Registered Scope:

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.

Original Registration Date: 2017-11-17 Effective Date: 2023-07-02 Expiry Date: 2026-07-01