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**

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; 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-11-17 Effective Date: 2020-07-02 Expiry Date: 2021-01-01

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

...making excellence a habit.™