

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Osang Healthcare Co., Ltd.

132 Anyangcheondong-ro,
Dongan-gu,
Anyang-si,
Gyeonggi-do
14040
Republic of Korea

Holds Certificate Number:

MD 793300

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostic reagents and instruments - Blood Glucose Monitoring System, Glycosylated Hemoglobin (HbA1C) Measuring System. The design, development, manufacture and distribution of immuno diagnostic reagent kits for infectious disease and molecular diagnostic reagent kits for infectious disease and genetic test.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-03-20

Latest Revision Date: 2024-03-20

Effective Date: 2024-03-20

Expiry Date: 2027-03-19



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