

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Abbott Diabetes Care Limited
Range Road
Witney
OX29 0YL
United Kingdom

DUNS Number: 76-347-7098

Holds certificate No:

MDSAP 699168

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

Design and development, production and distribution of blood glucose monitoring systems, blood glucose test strips, blood ketone test strips, control solutions, data management software, lancing device systems and lancets for self testing and healthcare professional use.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-10-23

Effective Date: 2018-10-23

Expiry date: 2021-04-28

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