Certificate of Approval

This is to certify that the Management System of:

Abbott GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany
MDSAP Facility Identifier: F003705

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

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

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820

David Derrick - Area Operations Manager UK & Ireland
Issued by: Lloyd's Register Quality Assurance Limited
for and on behalf of: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: LRQ0925480/B
Effective date: 2020 January 17
Expiry date: 2021 September 30
Certificate issue number: 10246648

Original approval:
MDSAP/ISO 13485 – 2018 October 1

Approval number: MDSAP – 0079011
The scope of this approval is applicable to:

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution of in-vitro diagnostic devices.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.