By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 773384 R000

Manufacturer: Abbott Diabetes Care Limited

Address:
Range Road
Witney
Oxon
OX29 0YL
United Kingdom

Single Registration Number: GB-MF-000029309

EU Authorised Representative: Abbott B.V.

Address:
Wegalaan 9
2132 JD Hoofddorp
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-10-16**

Current Issue Date: **2024-10-16**

Starting Validity Date: **2024-10-16**

Expiry Date: **2029-10-15**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

MediSense Glucose and Ketone Control Solution is an in vitro medical device intended for the automated quantitative glucose and ketone quality control test for a blood glucose and ketone meter and test strip. People with diabetes and their caregivers can use the control solutions to verify that the system is working correctly. Healthcare professionals can use the control solutions to check patients' blood glucose and ketone meters or facility meters are working correctly.

Risk Classification: Class C, self-test and Near patient test
Basic UDI-DI: 5021791MCS0001DZ
Type (Codes as per (EU) 2017/2185): IVR 0602

Device Name	Model
MediSense Glucose and Ketone Control Solutions	78623-01, 78687-01, 78689-01, 78616-01, 78688-01, 78725-01, 78726-01, 78727-01, 78728-01, 78729-01, 78730-01, 78807-01, 78808-01, 78809-01, 78810-01, 78811-01, 78812-01, 78813-01, 78814-01

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3702141	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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