

CERTIFICATE OF CONFORMANCE

Supplier Name: Bionostics Inc.

Product Name: (ADC) MEDISENSE CONTROL SOLUTION, GLU/KET, HI/LO
2 pack EN-GB/ES-LA/FR-FR/FR-CA/PT-PT/ES-ES/ZHT/DE/NL/IT/FI/PT-BR

Abbott Diabetes Care Cat. No. : 80139-20

Abbott Diabetes Care P/N and Rev.: PRT 8013920 Rev. G

Kit Lot Number: 11625 G Kit Exp. Date: 2021-03

Level(s): Low High

Customer Lot Number: 11620 G 11625 G

Bionostics Lot Number: MGK 90412 MGK 90403

Expiration Date: 2021-03 2021-03

Quantity Packaged: 59,877

Attach a copy of ADC Approval for Kit Packaging Certificate (M10123R1) YES NO

With this document, the manufacturer certifies this product conforms to the latest specifications and was manufactured in accordance with the requirements of 21 CFR Part 820 FDA Quality System Regulation, In vitro Diagnostics Directive 98/79/EEC and ISO 13485:2003 Standard under Canadian Medical Devices Conformity Assessment System (CMDCAS).

Inspection/Release Authorization: *Euphia Vorpas* Date: 05-06-19

Initials: KJ QC Packaging

BIOCOC-0049
Rev. A