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The purpose of this document is to provide additional information supporting the justification for permanent confidentiality of the User Manual for CU01A.

REQUEST FOR CONFIDENTIALITY - FCC

FCC ID: 2A663-CU01A

Pursuant to Sections 0.457(d) and 0.459 of the Commission's Rules and FCC Guidance document 726920, we hereby request permanent confidential treatment of User's manual.

REQUEST FOR CONFIDENTIALITY – ISED CANADA

IC: 28707-CU01A

Pursuant to Sections RSP-100 Paragraph 12.4 we hereby request permanent confidential treatment of User's manual.

Motivation for permanent confidentiality of User's manual

OnDosis develops the CU01 Control Unit, including the radio-enabled version CU01A, which can be configured for use with different drug products.

OnDosis collaborates with multiple pharmaceutical companies that use the CU01 device in combination with their respective drug products. Each pharmaceutical company is responsible for developing the user manual intended for the end user, based on a generic user manual provided by OnDosis.

To ensure patient safety, it is essential that patients refer only to the user manual provided by the relevant pharmaceutical company. This manual contains important drug-specific information as well as instructions on how to use the CU01 device correctly in connection with the administration of the specific drug product.

Consequently, the generic user manual developed by OnDosis is intended solely as a reference for the pharmaceutical companies and must be treated as confidential. It is equally important to ensure that only the appropriate drug-specific user manual developed by the pharmaceutical company is provided to and used by the end user.