

Mall-0426 v 2.0

# Certificate of Analysis

#### 1. Manufacturer

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

## 2. Description

Catalog no:

10-1195-01

Product:

Diabetes Sample Buffer

Lot no:

36341

Expiry date:

2027-10-08

## 3. Quality control

Quality control has been performed for lot no 36341 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

#### 4. Intended use

Mercodia Diabetes Sample Buffer is used for sample dilution for the following Mercodia ELISA assays: Human Insulin, Human Proinsulin, Iso-Insulin, Rat and Mouse Insulin, Rat/Mouse Proinsulin, Rat C-peptide and Animal Insulin.

# 5. Storage and handling

Recommended storage of Diabetes Sample Buffer is 2-8°C.

#### 6. Hazardous information

Please refer to the Material Safety Data Sheet for hazard identification.

#### 7. Quality standard documentation

The Mercodia Quality System fulfills the OSR and the requirements for the European CE mark, the Directive 98/79/CE on in vitro diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

#### 8. Names and signatures of certifying officers

Date of analysis:

Performed by:

Date of approval:

Date of approval:

2024-11-28

Performed by:

Maffias Jader gm. Jonan Mich Approved by:

2024-11-28

Performed by:

Maffias Jader gm. Jonan Mich Approved by:

Westberg Ew