EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER: Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH
Eiffestrasse 80, 20537 Hamburg, Germany

PRODUCT: Blood Gas and Chemistry Analysis System

MODEL:

Test Cartridge/BG8, BG3, BC4, BG4, BG9, BG10, BG5,BC6, BG9-Lac;Micro-BG8, Micro-BG3, Micro-BC4, Micro-BG4, Micro-BG9, Micro-BG10, Micro-BG5, Micro-BC6, Micro-BG9-Lac; MicroSample-BG8, MicroSample-BG3, MicroSample-BC4, MicroSample-BG4, MicroSample-BG9, MicroSample-BG10, MicroSample-BG5, MicroSample-BC6, MicroSample-BG9-Lac
Calibrant fluid pack/ CP50, CP100
Controls/Blood Gas and Electrolyte Control Level 1, Blood Gas and Electrolyte Control Level 2, Blood Gas and Electrolyte Control Level 3, Hematocrit Control High, Hematocrit Control Low

GMDN[Name/Code]:

Calibrant Fluid Pack/52859 calibrator
Test Cartridge/52858 multiple
Controls/52860 control

CLASSIFICATION: General/other device, devices other than those covered by Annex II and devices for performance evaluation, non-self-testing, according to article 9 of IVDD.

CONFORMITY ASSESSMENT ROUTE: Annex III

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: **IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN ISO14971:2019, EN 13612:2002, EN ISO23640:2015, EN ISO 17511:2020, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 62304: 2006+A1: 2015, EN 62366-1: 2015**

CE MARK CE

START OF CE-MARKING: 2013-07-10

PLACE, DATE OF ISSUE: SHENZHEN, 2023.6.30

SIGNATURE:

NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

Digitally signed by Bolea Petru
Date: 2023.11.24 13:35:08 EET
Reason: MoldSign Signature
Location: Moldova