



EDAN

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/ MODEL: Hematology Analyzer/ H30 Pro, H31 Pro, iH30 Pro
Reagents for Hematology Analyzer/ HD310 Diluent,
HL310Lyse, HC310 Cleaner,
ED-30D Hematology Controls,
ED-CAL PLUS Hematology Calibrator.

The accessories are used together with the product

EDMA[Name/Code]: CC Hardware + accessories + consumables + software/23.01.10.01.00
CBC-Reagents(Cleaning-/Diluting-/Lysing-/Sheat-fluids)/13.01.01.01.00
Blood Multilevel Controls/ 13.01.50.03.00
Whole Blood Calibrators/ 13.01.50.07.00

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: **EN ISO 14971: 2012, IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN 62304:2006 +A1: 2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002, EN ISO 17511:2003 ,EN ISO 23640: 2015**

CE MARK



START OF CE-MARKING: 2020-12-18

PLACE, DATE OF ISSUE: SHENZHEN, 2020.12.18

SIGNATURE:

NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

H30 Pro

3-Part Hematology Analyzer

Specification





Technical Specifications:

Principles

Direct impedance method for WBC, RBC and PLT counting
 Cyanide free Lyse reagent for hemoglobin test

Parameters

reportable parameters: WBC, LYM%, GRA%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, LYM, MPV, PCT, PLCC, PLCR, MID%, MID, GRA, PDW-SD, PDW-CV

2 RUO parameters: *NLR, *PLR

3 histograms for WBC, RBC and PLT

Note: RUO means for research use only.

Reagent

HD310 Diluent 10L/20L
 HL310 Lyse 200mL/500mL/1L
 HC310 Cleaner 50mL

Sample Volume

Whole blood mode	10 µL
Capillary Whole blood mode	10 µL
Pre-diluted mode	20µL

Performance

Parameter	Linearity Range	Precision (CV %)
WBC (10 ⁹ /L)	0.0-300	≤2.5% (3.50-15.00)
RBC (10 ¹² /L)	0.0-8.5	≤1.5%(3.50-6.50)
HGB (g/L)	0-250	≤1.5%(100-180)
PLT (10 ⁹ /L)	0-4000	≤5.0%(125-500)
MCV(fL)	70-120	≤1.0%(70.0-120.0)
HCT(%)	30-50	≤2.0%(30-50)

Throughput

60 samples per hour

Display

10.4 inch TFT color Touch Screen

Data Storage Capacity

100,000 results including results and histograms

60 QC files (100 data per file)

Communication

LAN Port supports HL7 protocol

Printout

Built-in thermal printer

External printer supported

Power Requirement

100V-240V, 50Hz/60Hz

Operating Environment

Temperature: 15°C~35°C;

Humidity: 20% RH~85% RH;

Air pressure: 70 kPa~106 kPa

Dimension and Weight

415mm x 275mm x 406mm (length x width x height) ;

Weight: 18kg



Edan Instruments, Inc.

No.15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District, Shenzhen
518122 P.R. China | +86.755.26898326 | www.edan.com.cn | info@edan.com.cn



CERTIFICATE OF TRAINING

Sergiu Sorocovici,

From "GBG-MLD" SRL, has successfully completed H30 pro, H60 series training courses including operation and maintenance, and is qualified to offer technical support for above mentioned products.

深圳市理邦精密仪器股份有限公司
EDAN INSTRUMENTS, INC.

赖晓宇

International Customer Service Manager

Date Nov 1st, 2023