



**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



# 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 1<sup>st</sup>, 2023