DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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 (Europe) Eiffestrasse 80 D-20537 Hamburg Germany
PRODUCT/MODEL:	**Pulse Oximeter/ H100B**
The accessories are used together with the product	
GMDN [NAME/CODE]:	Pulse oximeter, battery-powered /45607
CLASSIFICATION:	Class II b, Rule 10 According To Annex IX OF the MDD
CONFORMITY ASSESSMENT ROUTE:	Annex II excluding (4)

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 INCLUDING AMENDMENTS BY DERECTIVE 2007/47/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: **EN 60601-1:2006+A1:2013, EN 60601-1-2:2007/AC: 2010, EN ISO 80601-2-61:2011, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006, EN 62366:2008, EN 980: 2008, EN 1041:2008, EN ISO 780:1999**

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 17 05 91264 006 VALID UNTIL: 2022-09-17
START OF CE-MARKING:	2008-01-04
PLACE, DATE OF ISSUE:	SHENZHEN, 2017.9.12
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE