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 Eiffestrasse 80 20537 Hamburg Germany
PRODUCT/MODEL:	AMBULATORY BLOOD PRESSURE MONITOR / SA-10,SA-05,SA-06,SA-08 AND SA-09

The accessories are used together with the product

UMDNS [NAME/CODE]:	Recorders, Sphygmomanometers, Automatic / 16271
CLASSIFICATION:	Class IIa, 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 DIRECTIVE 2007/47/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE, THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC

STANDARDS APPLIED: **EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+AI:2015, EN 60601-1-11:2015, EN IEC 80601-2-30: 2019, EN ISO 81060-2: 2014, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006+A1:2015, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 780:2015**

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 091264 0006 Rev. 03 VALID UNTIL: 2022-09-17
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SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE