Digitally signed by Bunic Gheorghe
Date: 2021.07.23 23:06:52 EEST
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Location: Moldova

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

MANUFACTURER:	SHINVA MEDICAL INSTRUMENT CO., LTD, XINHUA MEDICAL SCIENTIFIC ZONE, ZIBO NEW & HI-TECH INDUSTRIAL DEVELOPMENT ZONE, 255086, ZIBO, SHANDONG, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Rapid Automatic Washer-Disinfector
MODELS:	Rapid-A-520, Rapid-M-320
CLASSIFICATION - ANNEX IX:	Ⅱb
CONFORMITY ASSESSMENT ROUTE:	Annex II excl. section 4 of Medical Device Directive

WE, SHINVA MEDICAL INSTRUMENT CO., LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
WE IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.
EN ISO 14971:2012, IEC 61010-1:2010+A1:2016,IEC 61010-2-040:2015, EN 61326-1:2013, EN ISO 15223-1:2016,EN 1041:2008, EN ISO 13485:2016, EN ISO 15883-1:2009+A1:2014, EN ISO 15883-2:2009,EN 62304:2006+A1:2015,IEC 62366-1:2015

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 003076 0002 Rev.02
EC REP **EUROPEAN REPRESENTATIVE:**	MedNet GmbH Borkstrasse 10,48163 MÜnster,Germany

START OF CE-MARKING: G1 003076 0002 REV. 02 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	Zibo,2019-12-11
SIGNATURE:	President