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:	H2O2 LOW TEMPERATURE PLASMA STERILIZER
MODELS:	PS-40X/PS-100X/PS-100XP/PS-100GXP/PS-200X/PS-200XP
CLASSIFICATION - ANNEX IX:	II B
GMDN CODE	40567
CONFORMITY ASSESSMENT ROUTE:	ANNEX II EXCL. SECTION 4 OF MDD 93/42/EEC

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, EN 61010-1:2010,EN 61010-2-040:2015, EN 61326-1:2013, EN ISO 15223-1:2016,EN 1041:2008, EN ISO 13485:2012, EN 62304:2006/AC:2008,EN 62366:2008,EN 62321:2013

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

START OF CE-MARKING: NO. G1 003076 0006 Rev.01, VALID TILL 2024-05-26.

PLACE, DATE OF DECLARATION:	ZIBO,2022-2-1
SIGNATURE:	Wang Yuquan, President

山东新华医疗器械股份有限公司
SHINVA MEDICAL INSTRUMENT CO.,LTD.

Digitally signed by Latîşev Anastasia
Date: 2024.03.16 19:02:08 EET
Reason: MoldSign Signature
Location: Moldova