DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Manufacturer:	Beijing Demax Medical Technology Co., Ltd. A13-7,Jingshengnansi Street,Tongzhou District,101102 Beijing ,PEOPLE'S REPUBLIC OF CHINA
Medical Device::	Name: Balloon In-deflation Device Model code : DID30(DMKID30),DID30S(OFF)(DMKID30S), DMKIDP30(REF.NO.DIDP30),DMKIDP30S(REF.NO.DIDP30S),DPD20, DPD20/OFF,DPD20/ON,DPD25, DPD25/OFF, DPD25/ON, DPD30, DPD30/OFF, DPD30/ON.
Classification - Annex IX:	Class Ⅰ, Rule2,Annex Ⅸ
Conformity Assessment Route:	Annex Ⅴ

WE, (BEIJING DEMAX MEDICAL TECHNOLOGY CO., LTD.) HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

WE AS THE MANUFACTURER ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST (APPENDIX I) OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany
Identification Number:	0123
(EC) Certificate(s):	G2S 063599 0022 Rev.02

EC REP

European Representative:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg GERMANY
Start of CE-marking:	2009-10-07
Place, Date of Declaration:	BEIJING ,2021-05-23

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.11 10:41:16 EEST
Reason: MoldSign Signature
Location: Moldova

Signature:

Name: HUAYING DAI
Position: GENERAL MANAGER

APPENDIX Ⅰ
EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated ”STERILE” - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
EN 1041:2008 Information supplied by the manufacture of medical devices
EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock Fittings
EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010
EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4:Selection of tests for interactions with blood(ISO 10993- 4:2002, including Amd 1:2006)
EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
EN ISO 10993-7 :2008/AC:2009 Biological evaluation of medical devices - Part 7 - Ethylene oxide sterilization residuals
EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993- 11:2017）
EN ISO 10993-12:2012 Biological evaluation of medical devices part 12 sample preparation and reference materials
EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO10993-18:2020)
EN ISO 11135-1:2007 Sterilization of health-care products - Ethylene oxide - Part 1:Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)
EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009
EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
EN ISO 13485: 2016/AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements(ISO 15223-1:2016, Corrected version 2017-03)

EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing Phthalate
EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986) EN 20594-1:1993/A1:1997
EN 62366:2008 Medical devices part 1: Application of usability engineering to medical devices (IEC 62366:2007)