Demax	Declaration of Conformity Push-Click Y Connector Kit	
	File No.：DMK/QS-QP29-QR01	Rev.: B/0

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:	Push-Click Y Connector Kit DPY01, DPY01B, DPY01R, DPY02, DPY02B, DPY02R, DPY03, DPY03B, DPY03R, DPY04B, DPY04R, DPY05
Classification - Annex IX:	Class Ⅱa, Rule2,Annex Ⅸ
Conformity Assessment Route:	Annex Ⅱ.3

WE, (BEIJING DEMAX MEDICAL TECHNOLOGY CO., LTD.) HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITED 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 (harmonized - 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):	G1 063599 0031 Rev.02
EC REP **European Representative:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany
Start of CE-marking:	2011-12-12
Place, Date of Declaration:	Beijing, 2020-08-28
Signature:	Name: HUAYING DAI Position: GENERAL MANAGER

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.07 14:39:15 EEST
Reason: MoldSign Signature
Location: Moldova

APPENDIX Ⅰ
EN 556-1:2001/AC: 2006 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
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 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 ISO 10993-1:2009/AC: 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
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
EN ISO 10993-12:2012 biological evaluation of medical devices part 12 sample preparation and reference materials
EN IS 10993-18:2020 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2020)
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 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)
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 11737-2:2020 Sterilization of medical devices - 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)
EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
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 62366:2008 Medical devices part 1: Application of usability engineering to medical devices