

Declaration of Conformity

Manufacturer Jiangsu Kanghua Medical Equipment Co., Ltd.
Address sanhekou,213115, Changzhou, Jiangsu,P.R.China

European Shanghai International Holding Corp. GmbH(Europe)
Representative Eiffestrasse 80, 20537 Hamburg Germany

Product Disposable catheter tip syringes
Model code appendix 1
Classification (MDD, Annex IX): I ms rule 2

Conformity assessment route: Annex V.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. **solely responsible for DOC.** Gamintojas atsakingas už šį dokumentą

DIRECTIVES

General applicable directives:

Medical device directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by Directive 2007/47/EC of 5 September 2007.

Standards Applied: appendix 2

Notified Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339
Munich, Germany

NB Identification number: 0123

Certificate: G2MS 0 45879 0017 Rev.01

Expiry date of the certificate: 2024-05-26 (It is valid till 31-December-2028 according to
Notified Body Confirmation Letter CL 045879 0026 Rev. 00)

Start of CE Marking: 2015-01-02

Place, date of issue: Jiangsu Kanghua Medical Equipment Co., Ltd.
sanhekou,213115, Changzhou, Jiangsu,P.R.China, 2015-01-02

江苏康华医疗器材有限公司

Signature JIANGSU KANGHUA MEDICAL EQUIPMENT CO., LTD.



Vienkartiniai kateter tipo švirkštai

Appendix 1

Specifications: 50mL/60mL; 100 mL, 120mL

Brand: Alfashield

Appendix 2

ISO 7886-1:2017	Testing Sterile Hypodermic Syringes	Sterilūs hipoderminiai švirkštai
EN ISO 14971:2019	Medial devices - application of risk management to medical devices	
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part1: Requirements for materials, sterile barrier systems and packaging systems	
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part2: Validation requirements for forming, sealing and assembly processes	
ISO11135:2014	Sterilization of health care products-Ethylene oxide-part 1:requirements for development, validation and routine control of sterilization process for medical devices	
MEDDEV. 2.12/1 :2013	MEDDEV Guidelines on a medical devices vigilance system	
MEDDEV. 2.7/1 :2016	MEDDEV clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/eec and 90/385/eec	
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes	
EN ISO11737-1: 2006	Sterilization of medical devices-Microbiological methods-Part 1:Estimation of population of microorganisms on products	
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 manufacturer of medical devices	
EN ISO15223-1: 2016	Graphical symbols for use in the labelling of medical devices	
EN 15986: 2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	
EN ISO 10993-1:2009	Biological evaluation of medical devices-Part 1 :Evaluation and testing within a risk management process	
EN ISO 10993-4:2017	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 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-11:2009	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
93/42/EEC:1993	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices