FORYOU 惠州华阳医疗器械有限公司
HUIZHOU FORYOU MEDICAL DEVICES CO., LTD

广东省惠州市东江高新科技产业园上霞北路1号华阳工业园B区13#厂房
No.1 Shangxia North Road, Dongjiang Hi-tech Industrial Park, Huizhou, Guangdong, China
电话：0752-5302000
传真：0752-5302020
邮编：516005
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MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.
Business address:	No.1 Shangxia North Road, Dongjiang Hi-tech Industrial Park, Huizhou City, Guangdong, China
Medical device(s):	Sterile Silicone Foam Dressing
Classification:	Class II b
GMDN code and term:	46854 - Dressing, wound-nonadherent, absorbent
Scope of application:	All batches to which the Full Quality Assurance Procedures have been applied

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	**TÜV SÜD Product Service GmbH, notified body no.0123:** European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Devices; No: G1 16 11 65520 029
Design examination certificate (if applicable):	Not apply.
Standards applied:	See Attached Schedule for multiple standards

Signature

Jinwen Mo
General Manager

20 January 2018
Date

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Attachment:

No.	Ref.	Reference and title of the harmonized standard (and reference document)
1	Directives	MDD 93/42/EEC COUNCIL DIRCTVIE 93/42/EEC of 14 June 1993 concerning medical devices
2		2007/47/EC Amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
3	Quality management system	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
4	Risk management	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
5	Packaging validation	EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+Amd 1.:2014)
6		EN ISO 11607-2:2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006+Amd 1.:2014)
7	Biological evaluation	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
8		EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
9		EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
10		EN ISO 10993-7:2008/AC:2009
11		ISO 10993-10:2010 Biological evaluation of medical devices —Part 10: Tests for irritation and delayed-type hypersensitivity
12		EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
13		EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
14	Sterilization	EN ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2014)
15		EN ISO 11138-2:2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

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No.	Ref.	Reference and title of the harmonized standard (and reference document)
16		EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2014)
17	Graphical symbols	ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
18		EN 980:2008 Symbols for use in the labeling of medical devices
19	Information supplied	EN 1041:2008 Information supplied by the manufacturer of medical devices
20	Determination of a population	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)
21		EN ISO 11737-1:2006/AC:2009
22		EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
23	Accelerated aging	ASTM 1980:2007 Standards guide for accelerated aging of sterile medical device packages
24	Clinical evaluation	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
25	Evaluation of clinical data:	MEDDEV. 2.7.1 Rev.4 Guidelines on medical devices evaluation of clinical data: a guide for manufacturers and Notified Bodies
26		MEDDEV. 2.12-2 Rev.2 Guidelines on medical devices of post market clinical follow-up studies: a guide for manufacturers and notified bodies
27	Vigilance system	MEDDEV 2.12-1 rev 8 Guidelines on a medical devices vigilance system
28	Product requirement	EN 13726-1:2002 Test methods for primary wound dressings - Part 1: Aspects of absorbency
29		EN 13726-1:2002/AC:2003
30		EN 13726-2:2002 Test methods for primary wound dressings - Part 2: Moisture vapor transmission rate of permeable film dressings