Feel+tech

CE 1370

Effective

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot. / device enclosed.

Unique identification number of the D.o.C: FT-DOC-001 Rev.2

MANUFACTURER:	FEEL TECH BIO Co.,Ltd. 1079-20, Charyeonggogae-ro, Gwangdeok-myeon, Dongnam-gu, Cheonan-si, Chungcheongnam-do,330-922 KOREA Tel. +82-41-522-2446
EUROPEAN REPRESENTATIVE:	CMC Medicaldevices & Drugs S.L. C/Horacio Lengo N 18 CP 29006, Málaga-Spain Tel. +34951214054
PRODUCT (Model/type):	Sterile Single Use Insulin Syringe [Feel Ject Insulin Syringe (=FMS(Fine Micro Syringe), Accusure Kim, Omnican N, Elasty]
CLASSIFICATION:	Ⅱa
RULE TO BE APPLIED:	6
CONFORMITY ASSESSMENT ROUT:	Annex Ⅱ.3 (Full Quality Assurance System)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	Refer to the Attachment.
NOTIFIED BODY:	Notified Body Number 1370, Bureau Veritas Italia S.P.A Viale Monza, 347 20126- MILANO Country : Italy
(EC) CERTIFICATE(S):	-
START OF CE-MARKING	-
PLACE, DATE OF ISSUE:	In Cheonan-si, Mar. 10, 2019
SIGNATURE:	Bu Sool Kim / President

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Attachment.

European Norms and Standards and other Documents supporting Technical Files;

No.	Harmonized Standard	Standard Name
1	EN ISO 13485 : 2016	Medical devices - Quality management systems – Requirements regulatory purposes (ISO 13485 :2016)
2	EN ISO 14971 : 2012	Medical devices - Application of risk management to medical Devices (ISO 14971:2007)
3	EN 1041 : 2008+A1:2013	Information supplied by the manufacturer with medical devices
4	EN ISO 10993-1:2009	Biological evaluation of medical devices Part 1 : Evaluation and testing
5	EN ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests of interactions with blood
6	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7	EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
8	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
9	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
10	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
11	EN ISO 11607-1:2017 /A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
12	EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
13	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 11135:2014)
14	EN ISO 11737-1:2015	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO11737-1:2006/Cor 1:2007)
15	EN ISO 11737-2:2015	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)

Attachment.

16	EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirement for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
17	EN ISO 14644-1:2015	Clean rooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
18	EN ISO 14644-2:2015	Clean rooms and associated controlled environments – Part2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
19	EN ISO 9626 :2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO 9626:2016)
20	EN ISO 7864 : 2016	Sterile hypodermic needles for single use - Requirements and t est methods (ISO 7864:2016)
21	MEDDEV.2.7.1 Rev.4:2016	Clinical Evaluation : A guide for manufacturers and notified bodies
22	MEDDEV.2.12_1 Rev.8:2013	Guidelines on a medical device vigilance system
23	EN ISO 14155:2011 , AC/:2011	Clinical investigation of medical devices for human subjects – Good clinical practice(ISO 14155:2011) – Technical Corrigendum 1(ISO 14155:2011/Cor 1:2011)
24	EN ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2016)

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