Document Title:	**EU Declaration of Conformity of Pen Injector**
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Revision:	A/4
Author:	Haixiang Xin
Date:	24st, Feb, 2025

	Signature	**Date**
Arranged by:	Haixiang Xin	24st, Feb, 2025
Reviewed by:	Chengdong Niu	24st, Feb, 2025
Approved by:	WeitaoXiao	24st, Feb, 2025

REVISION STATUS:

Version	Brief Description of Revision	Author	Date*(DD MMM YYYY)*
A/0	New Procedure	Haixiang Xin	20th, Jun, 2022
A/1	Add EN ISO 10993-12:2021 in the Applied Standards/Common Specifications (CS) List	Haixiang Xin	10th, July, 2023
A/2	Add CE certificate information	Haixiang Xin	1st, Sep, 2023
A/3	Add EN ISO 10993-18:2020	Haixiang Xin	31st, Oct, 2023
A/4	Update the version number of the product standards EN ISO 11608-1 and ASTM D4169	Haixiang Xin	24st, Feb, 2025

EU Declaration of Conformity

Manufacturer: Beijing Fert Technology Co., Ltd..

Address: 1st and 2nd floors of Building 3, Building 4, Courtyard 23 Panlong West Road, Mafang Town, Pinggu District, Beijing P. R. China

Tel.: +86-10-80910666 Fax: +86-10-80910666

Website: en.china-fert.com

SRN: CN-MF-000009737

European representative: Lepu Medical (Europe) Cooperatief U.A.

Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands

Tel: +31-515-573399 Fax: +31-515-760020

SRN: NL-AR-000000551

Product: Pen Injector

Brand name: /

Device Nomenclature Code: A020203

Model List: See Annex 1

Applied Standards List: See Annex 2

Classification: According to Classification Rule 6, Annex VIII, classification rules of MDR, the device is considered to be a Class IIb medical device.

Conformity Assessment Route: Annex IX Chapter I, Section 2 and 3, Regulation (EU) 2017/745 (MDR)

Intended Purpose(medical Indications): Designed for a desire dose of insulin self-injection by diabetics and injection by professional caregiver. The pen injector uses 3.0 mL cartridges of insulin and a single use, detachable and disposable pen needle (supplied separately).

We hereby declare that the above-mentioned product meet the provisions of the Regulation (EU) 2017|745 (MDR) for medical devices. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body 0197, TÜV Rheinland LGA Products GmbH

CE 0197

Certificate	Initially issued	Last renewal	Valid until
HZ 2365565-1	2023-08-28	/	2028-08-27

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer: Beijing Fert Technology Co., Ltd.

Signed for and on behalf of : 

Name : **Weitao Xiao**

Function (Company) : **Person responsible for regulatory compliance**

Date : **24st, Feb, 2025**

Location : **Beijing**

Annex 1:

Catalogue Number List

Catalogue Number	Basic UDI	Type
Blue	69515921FT4801JG	BSZSQ-01
Green		

Accessories:

No accessories packaged with the device.

Annex 2:

Applied Standards/Common Specifications (CS) List

The standards/Common Specifications (CS) applicable for this product are listed as below:

Standard /Common Specifications (CS) No.	Standard/Common Specifications (CS) Name	Date of Issue	Full/Partial Compliance
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	2021-04-30	Full
EN ISO 11608-1:2022	Needle-based injection systems for medical use –Requirements and test methods—Part 1: Needle-based injection systems	2022-05-04	Full
EN ISO 11608-2:2022	Needle-based injection systems for medical use –Requirements and test methods—Part 2:Needles	2022-05-04	Partial
EN ISO 11608-3:2022	Needle-based injection systems for medical use –Requirements and test methods—Part 3:Finished containers	2022-05-04	Partial
EN ISO 10993-1:2020	Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process	2020-12-16	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity	2009-06-01	Full
EN ISO 10993-10:2023	Biological Evaluation of Medical Devices-Part 10:Tests for Irritation and Delayed-Type Hypersensitivity	2023-02-08	Full
EN ISO 10993-12:2021	Biological Evaluation of Medical Devices-Part 12: Sample preparation and reference materials	2021-06-16	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices -— Part 18: Chemical characterization of medical device materials within a risk management process	2020-05-27	Full
EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices	2021-12-31	Full
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021-07-01	Full
EN ISO 13485:2016+A11: 2021	Medical devices - Quality management systems - Requirements for regulatory purposes	2021-09-08	Full
IEC 62366-1:2020	Medical devices - Part 1: Application of usability engineering to medical devices	2020-06	Partial
ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems	2023-12-01	Full