Linkfar 山东连发医用塑胶制品有限公司
Shandong Lianfa Medical Plastic Products Co.,Ltd

EU Declaration of Conformity

Manufacturer: *whose single Authorized Representative:*

Shandong Lianfa Medical Plastic Products Co., Ltd. No.1Shuangshan SanjianRoad, Zhangqiu,Jinan City,250200 Shandong P. R. China SRN: CN-MF-000028790	Linkfar Healthcare GmbH Niederrheinstraße 71, 40474 Düsseldorf, Germany SRN: DE-AR-000005107

We, the manufacturer, herewith declare that the products information as follow：

Trade Name: Blood Lancets

Product Name: Blood Lancets

EMDN Code: V010402

Basic UDI-DI: 694951700V8

GIMA CODE	AMBISEA CODE	LIANFA CODE	Description
23916	RBL100-28G	01-1328-100	Lancets 28G -sterile - box of 100pcs-blue
23917	RBL25-28G	01-1328-25	Lancets 28G -sterile - box of 25pcs-blue
23918	RBL100-30G	01-1330-100	Lancets 30G- sterile - box of 100pcs-purple

Intended Use：

The Blood lancets is intended for capillary blood sampling in order to obtain a small blood sample for various tests. It is designed for use by both healthcare professionals and Lay users, providing a safe and convenient method for blood specimen collection in clinical and home healthcare settings.

meet the provisions of Regulation (EU)2017/745 which apply to them

The medical device has been assigned to class IIa according to Rule 6, Annex VIII of the Regulation (EU) 2017/745. It bears the mark

CE 0197

The product adopts the module of “EU Declaration of Conformity” and the conformity

EU Declaration of Conformity

assessment was performed according to Annex IV of Regulation (EU) 2017/745.
Compliance of the designated product with the Regulation (EU) 2017/745 has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: HZ 2492466-1

Issue date: 2024-04-03

Expiry date: 2029-04-02

Conformity assessment procedure: REGULATION (EU) 2017/745 Annex IX (Full QMS)

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

Applicable standard：

EN ISO 15223-1:2021; EN ISO 20417:2021; EN 556-1:2001/AC:2006; EN 556-2:2015; EN ISO 10993-1:2020; EN ISO 10993-4:2017;EN ISO 10993-5:2009;ISO 10993-10:2021;EN ISO 10993-11:2018;EN ISO 10993-23:2021;EN ISO 11137-1:2015/A2:2019;ISO 11137-2:2013/Amd 1:2022;EN ISO 11607-1:2020;EN ISO 11607-2:2020;EN ISO 11737-1:2018;EN ISO 11737-2:2020;EN ISO 14644-1:2015;EN ISO 14644-2:2015;EN 17141:2020;EN 62366-1:2015/A1:2020;EN ISO 14971:2019; EN ISO 10993-18:2020; EN ISO 7153-1:2016,ASTM D 4169-22; ASTM F 1980-21 MEDDEV 2.12/1,□MEDDEV 2.12/2 ,□MEDDEV 2.7/1 rev.4,□GHTF SG5 N1R7:2007,GHTF SG5 N2R8:2007,□GHTF SG5 N41R9:2005,□MDCG 2020-5,MDCG

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2020-6,□MDCG 2020-7,□MDCG 2020-8.

Common Specification (CS): N/A

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Lianfa Medical Plastic Products Co., Ltd.

Address: No.1Shuangshan SanjianRoad, Zhangqiu,Jinan City,250200，

Shandong P. R. China

Jinan, 2024-05-15 Lianying Yang|CEO

Place, date *Legally binding signature, Function*