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:Safety Lancets

Product Name:Safety Lancets

EMDN Code: V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE USE

Basic UDI-DI:

Model	Basic UDI-DI
PA	69495170PAHH

Description	GIMA code	AMBISEA code	LIANFA code
Round Safety lancet 18G (blade)1.8mm depth, box of 100pcs	24450	RASL1818	04-1818
Round Safety lancet 21G,2.2mm depth, box of 100pcs	24451	RASL2122	04-2122
Round Safety lancet 23G ,2.2mm depth , box of 100pcs	24453	RASL2322	04-2322
Round Safety lancet 26G,1.8mm depth, box of 100pcs	24454	RASL2618	04-2618
Round Safety lancet 28G,1.8mm depth, box of 100pcs	24455	RASL2818	04-2818

Intended Use：

PA The safety 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

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CE 0197

The product adopts the module of "EU Declaration of Conformity" and the 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 7864:2016;ISO 9626:2016; ASTM D 4169-22; EN ISO 23908-2013; 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 2020-6, MDCG 2020-7, MDCG 2020-8.

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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, 2025.06.06 — Lianying Yang|CEO

Place, date — *Legally binding signature, Function*