



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

Trade Name:Safety Lancets

Product Name:Safety Lancets

EMDN Code:V010401

Basic UDI-DI:

Model	Basic UDI-DI
PA	69495170PAHH

Ref No	Specification	Depth
04-2118	21G	1.8MM
04-2120	21G	2.0MM
04-2122	21G	2.2MM
04-2318	23G	1.8MM
04-2320	23G	2.0MM
04-2322	23G	2.2MM
04-2518	25G	1.8MM
04-2618	26G	1.8MM
04-2818	28G	1.8MM
04-3015	30G	1.5MM
04-1822	18G Blade	2.2MM
04-1818	18G Blade	1.8MM
04-1815	18G Blade	1.5MM
04-1720	17G Blade	2.0MM
04-1716	17G Blade	1.6MM
04-1712	17G Blade	1.2MM

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Intended Use:

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 Directive (EU)2017/745 which apply to them

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



The product adopts the module of “EU Declaration of Conformity” and the conformity assessment was performed according to Annex IV of Directive (EU)2017/745.

Compliance of the designated product with the Directive (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

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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.

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





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

Jinan, 2024-05-14

Place, date

Lianying Yang|CEO

Legally binding signature, Function