



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: Blood Lancets

Product Name: Blood Lancets

EMDN Code: V010402

Basic UDI-DI: 694951700V8

| Model | Specification |
|-------|---------------|
| I | 14G-33G |
| II | 14G-33G |
| III | 14G-33G |

| Description | GIMA code | AMBISEA code | LIANFA code |
|---------------------------------|-----------|--------------|-------------|
| Round Lancet 30G, box of 100pcs | 23918 | RBL100-30G | 01-1330-II |
| Round Lancet 28G, box of 25pcs | 23917 | RBL25-28G | 01-1328-II |
| Round Lancet 28G, box of 100pcs | 23916 | RBL100-28G | 01-1328-II |
| Round Lancet 32G, box of 100pcs | 23921 | RBL100-32G | 01-1332-II |

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





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

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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 10993-18:2020; EN ISO 7153-1:2016,ASTM D 4169-22; ASTM F 1980-21 MEDDEV 2.12/1, MEDDEV



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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

Jinan, 2025.06.06

Place, date

Lianying Yang|CEO

Legally binding signature, Function

