

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2492466-1

Manufacturer: Shandong Lianfa Medical Plastic Products Co., Ltd.
NO.1 Shuangshan Sanjian Road,
Zhangqiu, Jinan City,
250200 Shandong
P.R. China

EUDAMED Single
Registration No.: CN-MF-000028790

Products: Products of class IIa:
V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE-
USE
V010402 - LANCETS WITHOUT SAFETY SYSTEMS,
SINGLE-USE

Authorized representative(s): Linkfar Healthcare GmbH
Niederrheinstraße 71, 40474 Düsseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-04-03

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190147017-120

Effective date: 2024-04-03

Expiry date: 2029-04-02

Issue date: 2024-04-03



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zflg.de
BS-MDR-091



TÜVRheinland®
Precisely Right.