

Changzhou Chuangjia Medical Appliance Co., Ltd.

Add: Sanhekou Development Zone, Zhenglu Town 213115 Changzhou P.R. China

EC DECLARATION OF CONFORMANCE

We herewith declare that the below mentioned products are in conformance with the essential requirements of EC Council Directive and Standards. All supporting documentation is retained under the premises of the manufacturer and notified body.

Manufacturer Address	Changzhou Chuangjia Medical Appliance Co., Ltd. Sanhekou Development Zone, Zhenglu Town 213115 Changzhou P.R. China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.
Notified Body	TÜV SÜD product service GmbH Zertifizierstelle, Ridlerstraße 65, 80339 München-Germany
Notified Body ID Number	0123
EC Certificate Number	G2 076830 0008 Rev.02
Expiry date of Certificate	2024-05-26
Product	Hypodermic Syringes with or without needle
Brand	INJ/LIGHT
Classification (MDD 93/42, Annex IX)	Ila
Applicable Directives	Medical Device Directive (MDD 93/42 EEC)
Standard	ISO 13485, ISO 7886-1, ISO 7864, ISO 80369-7, ISO 6009, ISO 11138-2, ISO 15223-1, ISO10993, ISO 14971, ISO 11135 and all the standards about the essential requirements.

We confirm that the products is sterile and pyrogen free.

Date: 2022-10-27

Signature:

Xu Jia

