EC Declaration of Conformity according to MDD 93/42/EEC

Manufacturer: Tianjin Huahong Technology Co., Ltd.
Address: A01, Plant B, No.278, Hangkong Road,
Tianjin Pilot Free Trade Zone (Air Port Industrial Park),
Tianjin 300308, China

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Description: Sterile Lancets (Use with lancing device)

Model No's: I, II, III, IV,

Product Designation: Lancing Devices, Blood
UMDNS - Code: 10440

Classification (MDD, Annex IX) : IIa

Conformity Assessment procedure: Annex V

We, the manufacturer, herewith declare that the products listed above are in compliance with the provisions of Directive 93/42/EEC which apply to them.

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany (CE 0197)

Certificate No.: DD 60132408 0001

Issue date: 2018-12-20

Expiry date: 2023-08-24

This Declaration of Conformity covers all technology 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.

Chengzhe Cui, CEO

24th Jan, 2019
Date

Digitally signed by Şarco Alexandru
Date: 2022.11.25 15:02:41 EET
Reason: MoldSign Signature
Location: Moldova