

EC Declaration of Conformity

符合性声明



Name and address of the manufacturer:

Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang
District, Hangzhou City, 311121 Zhejiang, China

Name and address of the European
Authorized Representative:

Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert, Germany.
Tel: +49(0) 6894 581020
fax: +49(0) 6894 581021
e-mail: info@mt-procons.com

We declare under our sole responsibility that

the medical device:

Safety Lancets

UMDNS-code:

10440

UMDNS description (Device group):

Lancets, Blood

SL-21-12C, SL-21-18C, SL-21-20C, SL-21-22C, SL-21-24C, SL-
21-28C, SL-23-18C, SL-26-18C, SL-28-15C, SL-28-16C, SL-28-
18C, SL-28-20C, SL-30-15C, SL-30-16C, SL-30-18C, SL-30-22C.

Product specification:

SL-21-12T, SL-21-18T, SL-21-20T, SL-21-22T, SL-21-24T, SL-21-
28T, SL-23-18T, SL-26-18T, SL-28-15T, SL-28-16T, SL-28-18T,
SL-28-20T, SL-30-15T, SL-30-16T, SL-30-18T, SL-30-22T.

SL-21-12M, SL-21-18M, SL-21-20M, SL-21-22M, SL-21-24M, SL-
21-28M, SL-23-18M, SL-26-18M, SL-28-15M, SL-28-16M, SL-28-
18M, SL-28-20M, SL-30-15M, SL-30-16M, SL-30-18M, SL-30-22M.

of class:

Ila.according to annex IX of directive 93/42/EEC: **Rule 6**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

Directive 93/42/EEC Annex V.

Registration no.:

DD 2091024-1

Issue date:

2020-11-17

Expiry date:

2023-10-22

Name and address of the Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.

Notified body number :

0197

Place and date

Hangzhou, 2020.11.23

Name and function

Zearou Yang / RA
Zearou Yang / Regulatory Affairs Manager