



EC Declaration of Conformity

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Manufacturer:

ANDON HEALTH CO., LTD.
No.3 JinPing Street, Ya An Road, Nankai
District, Tianjin, China

whose single Authorized Representative:

Lotus Global Co., Ltd.
1 Four Seasons Terrace, West Drayton,
Middlesex, London, UB7 9GG, United Kingdom

We, the manufacturer, herewith declare that the products

TENSE DEVICES

UMDNS-Code: 13-782;

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II 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
Certificate No.: HD 60132189 0001
Issue date: 2018-08-30
Expiry date: 2019-11-05

Following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

ANDON HEALTH CO., LTD.
No.3 JinPing Street, Ya An Road, Nankai District, Tianjin, China

Tianjin / 2018-9-14
Place, date

Helen Nie / MK
Legally binding signature, Function