

## **EC Declaration of Conformity**

Manufacturer:

whose single Authorized Representative:

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We, the manufacturer, herewith declare that the products

Steam Sterilizer - TANZO E series

UMDNS-Code: 13746; GMDN-Code: 38671

meet the provisions of Directive 93/42/EEC and 2007/47/EEC which apply to them.

The medical device has been assigned to class IIb according to rule 15 Annex IX of the Directive

93/42/EEC. It bears the mark

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) 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 Product GmbH -**Tillystraße 2-90431 Nürnberg **Identification Number: 0197**

> > Certificate No.: HD 60108780 0001 Issue date: 2016/03/28

Expiry date: 2021/03/16

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding Section 4) 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

