

# EC Declaration of Conformity

Manufacturer:

**Shenzhen Combei Technology Co., Ltd**  
11-5B, No. 105, Huan Guan South Road, Dahe  
Community, GuanLan, Long Hua New District  
ShenZhen, P.R.C

whose single Authorized Representative:


**MedNet EC-REP GmbH**  
Borkstrasse 10, 48163 Münster, Germany

We, the manufacturer, herewith declare that the products

Manufacturer model names	Distributor model covered by this Declaration of Conformity	UMDNS-code
NC100	IRT-80	14-036

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

The medical device has been assigned to class IIa according to Annex II 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 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

**TÜ V Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**  
Certificate No.: HD 2111011-1  
Issue date: 2021-03-22 , Expiry date: 2024-05-26

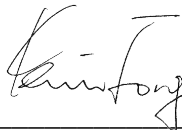
following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

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

## SHEN ZHEN COMBEI TECHNOLOGY

11-5B, No. 105, Huan Guan South Road, Dahe Community, GuanLan, Long Hua New District  
ShenZhen, P.R.C



Kevin Fong, Management Representative



EC Declaration of Conformity  
CB20210618-01