File No.: SDT-DEL-202109003

## **EC Declaration of Conformity**

Manufacturer:

Shenzhen Dongdixin Technology Co., Ltd.

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Industrial Estate Xilixiaobaimang 518108

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**Authorized Representative:** 

Shanghai international holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg Germany

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DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Non-Contact Forehead Thermometer TH1009N

(including system components and accessories)

UMDNS-Code: 14036

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

C €0197

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 have been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2 - 90431, Nürnberg, Germany

Certificate No.: HD 60147882 0001 Issue date: 03 Aug. 2020 Expiry date: 26 May. 2024

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

Company: Shenzhen Dongdixin Technology Co., Ltd.

Address: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate Xilixiaobaimang 518108 Nanshan District, Shenzhen P. R. China

2021-9-7, Shenzhen

Place, date

Jianping Kang, Vice president
Legally binding signature, Function