

EC declaration of conformity

for the product Thermo Distance / IR Forehead Thermometer **TH1009N**

We, Société Terraillon S.A.S., 1 rue Ernest Gouin, 78290 Croissy sur Seine, France, declare under our sole responsibility that product indicated above is compliant with essential requirements of health, safety and performances. This product complies with requirements of the **Directive 93/42/EEC concerning medical devices** and complies with the standards listed below:

| | |
|------------------------------|--|
| Report QETH1009NXS20123011-1 | IEC 60601-1 :2012/EN60601-1 :2006+A11 :2011+A1 :2013 |
| Report GZME 160200013301 | IEC 60601-1-2 |
| Report GZME 17057174001 | IEC 60601-1-11 :2015 |
| Report QETH1003NXS20123011-2 | ISO 80601-2-56 :2009 |

Notified Body :

TÜV Rheinland LGA Product Gmbh
Tillystrasse 2 – 90431, Nürnberg, Germany
Certificat N°: HD60110846 0001
Issue date : 22 juin 2016
Expiry date 20 juin 2021

Manufacturer :

Shenzhen Dongdixin Technology Co, Ltd
N°. 3 Building XiliBaimang Xusheng
Industrial Estate, 518108 Nanshan
Shenzhen China

Authorized representative :

Shanghai international holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

This product carries the CE mark **CE 0197** which was first affixed in 2019

Croissy sur Seine, 02/07/2020

Frederic DAGGAG
Quality Manager

