

# EC Declaration of Conformity

Certificate No.: ML150508001

*Manufacturer:*  
**Microlife Corporation**  
9F, 431, RuiGuang Road, NeiHu,  
Taipei, 11492, Taiwan, R.O.C.

*whose single Authorized Representative:*  
**Microlife AG**  
9443 Widnau / Switzerland

We, the manufacturer, herewith declare that the products

**Products:** **UMDNS**  
**Thermometers, infrared, Forehead(FR1MR1)** **14-036**

meet the provisions of Directive 93/42/EEC amended by 2007/47/EC Article 5 & Annex I which apply to them.

The medical device has been assigned to class IIa according to Annex IX Rule 10 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

**TÜV NORD CERT GmbH**  
**Langemarckstr. 20, D-45141 Essen**  
Certificate No.: 04 232 950010  
Validity from: 2013-10-06  
Expiry date: 2016-10-21

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC. and in conformity to the following standards or other normative documents:

ASTM E1965-98:2009  
EN 12470-5:2003  
EN ISO 80601-2-56:2009  
EN 60601-1:2006+A1:2013(IEC 60601-1:2005+A1:2012)  
EN 60601-1-2:2007/AC:2010(IEC 60601-1-2:2007)  
EN 60601-1-11:2011(IEC 60601-1-11: 2010)  
EN 62304:2006/AC:2008(IEC 62304:2006)  
EN 60601-1-6:2010(IEC 60601-1-6:2010)  
EN ISO 10993-1:2009/AC: 2010(ISO 10993-1:2009+ COR.1:2010)  
EN ISO 10993-5:2009(ISO 10993-5:2009)  
EN ISO 10993-10:2010(ISO 10993-10:2010)  
EN ISO 10993-12:2012(ISO 10993-12:2012)  
EN ISO 14971:2012(ISO 14971: 2007)  
EN 980:2008  
EN 1041:2008

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

**Microlife Corporation**

Gary Huang, Management Representative

Issued Date