

# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



**MANUFACTURER: FAMIDOC Technology Co., Ltd.**

No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Dongguan,  
Guangdong Province, 523853,China.

**MEDICAL DEVICE:** Infrared thermometer (Model:FDIR-V12)

**CLASSIFICATION - ANNEX IX:** CLASS IIA, RULE 10

**UMDNS/DMDNS:** 14036 Thermometers, Infrared

**Conformity assessment Route:** Annex II (Excluding Section 4) - EC DECLARATION OF  
CONFORMITY (Full quality assurance)

We, **FAMIDOC Technology Co., Ltd.**, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC.

**Standards applied:** EN ISO 13485:2016, EN ISO 14971:2012, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2015, EN60601-1-11:2015, EN ISO 80601-2-56:2017+A1:2020, EN 62304:2006 +A1:2015, EN 62366-1:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 15223-1:2021; EN ISO 20417:2021, EN ISO 780:2015.

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**Identification number:**  1639

**(EC) Certificate(s):** CN19/41052

**Start of CE-marking:** 16 December, 2019



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**Place, Date of Declaration:** DONGGUAN, July 19, 2022

Singed on behalf of  
FAMIDOC Technology Co., Ltd

Amos Zou

**Title:** Management Representative