



DECLARATION OF CONFORMITY

Kraków, 05/11/2020

Manufacturer: Hunan Honggao Electronic Technology Co., Ltd

Block 5, Comprehensive Industrial Park, Tenghui Pioneer Park, Nanxian Economic Development Zone, Yiyang, Hunan Province, China

Distributor: Platinet SA, Ul. Tadeusza Śliwiaka 48 30-798 Kraków

Importer: Platinet Electronics SRL, 077065 Corbeanca, Jud Ilfov, Str. Piscului 10A/2, Romania

Notified Body No.1282

Ente Certificazione Macchine Add: P.IVA 02604150363

Via Cà Bella 243, 40053 Valsamoggia - Location Castello di Serravalle (Bo) Italy

Name:

Non-contact infrared thermometer, models: HG01, HG02

The above-mentioned subject of this declaration complies with the relevant requirements of the EU harmonization legislation: the Medical Device Directive 93/42/ EEC.

They comply with the provisions of the following CE directives: LVD 2014/35/EU, EMC 2014/30/EU, RoHS 2011/65/EU & EU No. 2015/863

And meets the requirements of the following standards:

EN 60601-1-: 2006+A11:2011+A1:2013+A12:2014

EN 55011:2016+A1:2017

EN 6061-1-2:2017

EN 61000-3-2:2014

EN 61000-3-3:2013

EN 60601-1-: 2006+A11:2011+A1:2013+A12:2014

IEC 62321-1:2013, IEC 62321-2:2013, IEC 62321-3-1:2013, IEC 62321-3-2:2013, IEC 62321-4:2013

IEC 62321-5:2013, IEC 62321-6:2015, IEC 62321-7-1:2015, IEC 62321-7-2:2017, IEC 62321-8:2017

MDD 93/42/EEC: 2007, ISO14971: 2012, EN60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN1041:2008, EN ISO 15223-1:2016, MEDDEV 2.7.1 Rev.4: 2016, EN ISO 10993- 1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010, IEC/TR 60878-2015, ENISO780: 2015, EN 62366:2015, EN 62304:2006/AC:2008, EN ISO 80601-2-56:2017, ASTM E1965: 2009

Hereby, Platinet declares that the above-mentioned products are in compliance with the essential requirements and other relevant provisions of the CE directives: LVD 2014/35 / EU EMC 2014/30 / EU, RoHS 2011/65 / EU & EUNo. 2015/863.

The device can be used in Poland.

The last two digits of the year when CE was affixed: 20

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IMPORT

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