

杭州华安医疗保健用品有限公司

HANGZHOU HUA'AN MEDICAL & HEALTH INSTRUMENTS CO., LTD

EU Declaration of Conformity according to the Medical Devices Directive 93/42/EEC

Manufacturer

Hanzhou Hua'an Medical & Health Instruments Co., Ltd.

Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, Hangzhou, Zhejiang 310023 China

European representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany

Product list:

Product name	Model					
Digital Thermometers	DT-01A	DT-11A	DT-02	DT-101A	DT-K01A	DT-Y111D
	DT-01B	DT-11B	DT-12	DT-111A	DT-K11A	
	DT-01D	DT-11D		DT-101B	DT-K101A	
	DT-01E	DT-11E		DT-111B	DT-K111A	
	DT-01G	DT-11G		DT-111D	DT-K11B	
		DT-11H		DT-111G	DT-K111B	
					DT-K111D	
					DT-K11E	
Infra Red Ear Thermometers	ET-100A, ET-100B, ET-100D, ET-100E, ET-100G, ET-100I, ET-100J					
Infra red forehead thermometer	FT-100A, FT-100B, FT-100D, FT-100E					
Digital Sphygmomanometers	MW-300A, MW-300B, MW-300C, MW-300D, MW-300E, MB-300A, MB-300B, MB-300C, MB-300D, MB-300F, MB-300H, MB-300I					

Classification (MDD, Annex IX): IIa

Conformity Assessment Route: Annex II(excluding section 4) of Directive 93/42/EEC

We here with declare that the above mentioned products meet the provisions of the above EC Council Directives. All supporting documentation is retained under the premises of the manufacturer.

Applicable Standards:

Digital Thermometers Harmonized standard	Infra-red Ear Thermometers Harmonized standard	Infra-red forehead Thermometers Harmonized standard	Digital sphygmomanometers Harmonized standard
EN ISO 15223-1:2016 EN 1041:2008+A1:2013 ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN 12470-3:2000+A1:2009 EN 60601-1:2006+A11:2011+A1: 2013+A12:2014 EN 60601-1-11:2015 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 62366:2008 +A1:2015 EN 62366-1:2015 ISO 80601-2-56-2017AMD.1:201 8 IEC 62304:2015	EN ISO 15223-1:2016 EN 1041:2008+A1:2013 ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN 12470-5:2003 EN 60601-1:2006+A11:2011+A1: 2013+A12:2014 EN 60601-1-11:2015 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 62366:2008 +A1:2015 EN 62366-1:2015 ISO 80601-2-56-2017AMD.1:201 8 IEC 62304:2015	EN ISO 15223-1:2016 EN 1041:2008+A1:2013 ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN 12470-5:2003 ASTM E 1965-98 EN 60601-1:2006+A11:2011+A1: 2013+A12:2014 EN 60601-1-11:2015 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 62366:2008 +A1:2015 EN 62366-1:2015 ISO 80601-2-56-2017AMD.1:201 8 IEC 62304:2015	EN ISO 15223-1:2016 EN 1041:2008+A1:2013 ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN 1060-3:1997+A2:2009 EN 1060-4: 2004 EN 60601-1:2006+A11:2011+A1: 2013+A12:2014 EN 60601-1-11:2015 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 62366:2008 +A1:2015 EN 62366-1:2015 EN 62366-1:2015 IEC 80601-2-30-2018 IEC 62304:2015

Notified Body: TÜV Rheinland LGA Products GmbH
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EC Certificate: HD 60135526 0001

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Manager

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