TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60128797 0001

Report No.: 15060021 007

Manufacturer:
Dong E E Hua Medical Technology
Co., Ltd.
No.29 XiangJiang Road
Dong-E County
252201 Shandong
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60085195 0001

Expiry Date: 2023-05-29

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-05-30

Date: 2018-05-18

Notified Body LGA Products GmbH

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Azarov Tatiana
Date: 2021.07.01 10:28:38 EEST
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: DD 60128797 0001
Report No.: 15060021 007

Manufacturer: Dong E E Hua Medical Technology
Co., Ltd.
No.29 XiangJiang Road
Dong-E County
252201 Shandong
China

Products:

- Digital Thermometers
- Electronic Sphygmomanometers

Aspects of manfacture concerned with conformity of products with metrological requirements:

- Mercury-Free Clinical Thermometers

Site included:

South of Liaohua Road, East of Dong-e County,
Shandong Province 252201, P.R. China

Mercury-Free Clinical Thermometers

Notified Body

Date: 2018-05-18

X. Ren

Declaration of Conformity

We, the Manufacture and exporter of

DONG E E HUA MEDICAL TECHNOLOGY CO.,LTD.

ADD: NO.29,XIANGJIANG ROAD,DONG-E COUNTY, SHANDONG PROVINCE 252201 CHINA

TEL: +86-635-3265983

FAX:+86-635-3265993

Declare under our sole responsibility that the product

MERCURY-FREE CLINICAL THERMOMETER

To which this declaration relates is in conformity with the following standard(s) or other normative document(s)

EN ISO 13485:2016

(Title and/or number and date of issue of the standard(s) or other normative documents, if applicable)

Following the provisions of Directive

93/42/EEC, Special Class I

Notified Body: TUV Product Service Ltd

EU Representative: Prolinx GmbH

Address: Brehmstr.56,40239 Duesseldorf Germany

DONG E(CHINA),2020/01/31

(Place and date of issue)

WANG WEIJIAN

(Name and signature of equivalent marking of authorized person)

AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						DONG E E HUA MEDICAL				
DMD002675988	TERMOMETRU FĂRĂ MERCUR		CLINIC		China	DONG E E HUA MEDICAL TECHNOLOGY CO., LTD.	Î.M. BECOR S.R.L.	Rg04-000036	17-02-2020	

✓ [Producatorul] Равно 'DONG E E HUA MEDICAL TECHNOLOGY CO., LTD.' Очистить

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133013 0001

Report No.: 15067271 006

Manufacturer:
Hangzhou Universal
Electronic Co., Ltd.
298 Yunxi Road, Cangqian Street
Yuhang District
Hangzhou
311121 Zhejiang
China

Products:
- Digital Thermometers
- Blood Pressure Monitors
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear / Forehead Thermometers

Replaces Approval, Registration No.: DD 60110599 0001

Expiry Date: 2023-11-06

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-08-08

Date: 2019-08-08

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH · Tillystraße 2 · 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

MINISTERUL SĂNĂTĂȚII, MUNCII ȘI PROTECȚIEI SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chișinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: ansp@ansp.md; anticamera@ansp.md

DOCUMENTAȚIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828

Centrul de încercări de laborator acreditat de către Centrul Național de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2016 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătății, Muncii și Protecției Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR
PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. P - 8556/2021

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 13 " ianuarie a./*г.* 2021

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea și desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Articole parafarmaceutice – halate pentru vizită, mărimea L, XL
termometru digital cu capăt flexibil, rigid

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* **(se va indica denumirea completă a Regulamentului (lor) sanitar (e) /** *указать полное наименование санитарного (ых) регламента (ов)*

Indicații Metodice nr.29 FȚ/1683 din 14.05.01, Directiva Europeană 93/42/EEC privind dispozitivele medicale, HG nr.702/2018 din 11.07.2018, Regulamentul (UE) 2016/425 privind echipamentele de protecție individuale

Organizația-producătoare/importatoare, țara de origine / *организация произв./импортер, страна происхождения*

China, SUZHOU ACMED IMPORT&EXPORT CO., LTD.

Destinatarul avizului sanitar / *получатель санитарного заключения*

ÎM „BECOR" SRL, Moldova Chișinău, str. Calea Orheiului, 111/5

Ca temei pentru recunoașterea conformității produselor Regulamentului (lor) sanitar (e) menționat (e) a servit / *Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило*

Demers, contract f/n din 31.10.2016, facturi, certificat de calitate, raport a încercărilor de laborator nr.8777 din 05.01.2021

(a enumera documentele de însoțire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)* **Normativul sanitar /** *санитарный норматив*

conform raportului încercărilor de laborator nr.8777 din 05.01.2021

Domeniu de utilizare / *Область применения:* scopuri medicinale

Condițiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
importul, plasarea pe piață în condițiile respectării legislației în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 30 ianuarie 2022

Int.

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ
Vasile GUȘTIUC
(numele, prenumele/ Ф.И.О.)

L.Ș. (semnătura / подпись)

ANSP/HAO3

SP **10-XVI-09** 00038 **03**

ex:Șt.Constantinovici
tel: 574 679

EC Declaration of Conformity

Manufacturer: Wuxi Medical Instrument Factory Co., Ltd.

Add:No.43 Xixin Road,Zhangjing,Xibei town,Wuxi city,Jiangsu,214194 China

European representative : Lotus NL B.V.

Add: Koningin Julianaplein 10,1e Verd,2595AA,The Hague,Netherlands.

Tel: 0031626669008

Product: Mercury free Clinical thermometer

Model: CR.W00

Classification: Im According to Rule 5, Annex IX of MDD 93/42/EEC amended by 2007/47/EC

Harmonized Standards:

EN ISO 15223-1:2012, EN 1041:2008, EN ISO 14971:2012, EN 12470-1:2000+A1:2009, GB1588:2001, ISO 719:1985.

Conformity Assessment Route: Annex V, MDD 93/42/EEC amended by 2007/47/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body: INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Address: trida Tomase Bati 299, Louky, 763 02 Zlin Czech Republic

EC certificate No.: 19 0248 QS/NB

Date of issue:2019-05-22

date of validity:2024-05-21

Version:H

Ding Yan Ping/ General Manager

Signature: Ding Yanping

Date: 2019.05.23

REPUBLICA MOLDOVA IDNO 1003600056028 S.R.L. «BECOR» PENTRU FACTURI INTREPRINDEREA MIXTA CHISINAU

WUXI MEDICAL INSTRUMENT FACTORY CO.,LTD.
无锡市医用仪表厂有限公司

AGENTIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000283770						WUXI MEDICAL INSTRUME				
DM000283770	TONOMETRU MECANIC CU STETOSCOP		CLINIC +S		China	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD	Î.M. BECOR S.R.L.	Rg04-000256	07-10-2020	

✓ [Producatorul] Равно 'WUXI MEDICAL INSTRUMENT FACTORY CO., LTD' И [Cod] Равно 'DM000283...

Очистить

REPUBLICA MOLDOVA mun. CHIȘINĂU IDNO 1008600058828 S.R.L. «BECOR» PENTRU FACTURI INTREPRINDEREA MIXTĂ

rossmax	EC Declaration of Conformity	Doc No.	RD-4-002
		Version	I
		Page	1/2
		Effective Date	2014/02/14

1. EC Declaration of Conformity

Manufacturer	:	Rossmax Swiss GmbH
Address		Tramstrasse 16, CH-9442 Berneck, Switzerland
Notified Body	:	SGS United Kingdom Limited
Address	:	202B Worle Parkway
		Weston-Super-Mare, BS22 6WA United Kingdom
EU Identification No.	:	0120
Certificate No.	:	TW14/10344.03
Product type	:	Non-Invasive Blood Pressure Measuring Device
Type Designation	:	AB701f, AB761f, AC701k, AC1000f, AD761f, AE701f, AF701f, AJ701f, AK101f, AK150f, AK151f, AU941f, AV91, AV151f, AV351f, AW91, AW150f, AW151f, AW175f, AX356f, BA701, BC351, BD701, BE701, BF701, BI701, BK150, BK400, BM75, BQ705, BR705, BS705, BT705,, BU705, BV705, C381, C400, CD91, CD155f, CF155f, CF175f, CF701k, CF707f, CF761f, CG155f, CG175f, CH91, CH155f, CJ766f, D150, D400, DM430, G150, GA100, GA101, GA102, GA112, J400, J400CA, J401, K150, K350, K400, LC150, LC400, Mandaus II, MA90, MA91, MA175f, MA350f, MA351f, MA801f, MB303, MC100f, MC101, MG40, MG150f, MG151f, MH150f, MH150fCA, MH151f, MH901f, MJ90, MJ91, MJ150f, MJ151f, MJ400i, MJ700i, MJ701f, MJ701i, MK381f, MN95, MN601f, MO701i, MP150f, MP151f, MR801f, MR800iPC, MS60, MS150f, MS151f, MS400i, MV801f, MW701f, MW701k, MW821f, O400, P400, RM200, RS380, RW450, S150, S380, T400, T401, V701, W381, X1, X3, X4, X5, X7, X9, X400, Cone cuff, DK cuff, Medical cuff
Conformity Assessment	:	EU Council Directive 93/42/EEC Annex II (excluding Section 4)
Classification	:	Class IIa (According to EU Council Directive 93/42/EEC, Annex IX, Rule 10)
Serial No.	:	YY M 001 - 000001

YY → Manufacturing year.
M → Manufacturing month.
001 → Lot sequential number
000001 → Sequential number

The above-mentioned devices are in full compliance with the relevant provisions of EU Council Directive 93/42/EEC amended by 2007/47/EC, Annex I-Essential Requirements and applied harmonized standards, national standards or other normative documents.

EN 980 : 2008, EN 1041: 2008, EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, EN 1060-4:2004, EN ISO 10993-1:2009/ AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 14155:2011, EN ISO 13485:2012/AC: 2012, EN ISO 14971:2012, EN 60601-1:2006/ AC2010, EN 60601-1-2:2007/ AC2010, EN62304:2006/ AC2008, EN 60601-1-6:2010, EN62366:2008, EN60601-1-11: 2010.