

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

ВНОСИТЕЛ: "Щайнбергер" ООД
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Производител: Shanghai Huazhe International Trade Co., Ltd
Suite 602, Cimic Tower, 1090 Century Avenue,
Pudong, Shanghai, China

Продукт: Апарат за измерване на кръвно налягане

Модел: KD-xxx, MW-300

В съответствие със следните европейски директиви:

- Наредба за съществените изисквания и оценяване на съответствието за електромагнитна съвместимост 89/336/ЕЕС и 2004/108/ЕС.
- 93/42/ЕЕС - Медицински устройства

Декларирам, че този продукт е оценен и съответства на следните приложими стандарти:

БДС EN 60601-1-2:2001+A1:2004 Електромедицински апарати. Част 1-2: Основни изисквания за безопасност. Допълващ стандарт. Електромагнитна съвместимост.

Test report: JSH 05110154-001

подпис:



/д-р Стефан Дервишев/
управител

София, 25 юли 2009 г.

Intertek ETL SEMKO

VERIFICATION

of conformity with European Directives

Order No. JSH 05110154
Type of equipment ELECTRONIC BLOOD PRESSURE MONITOR
Applicant /Manufacturer SHANGHAI HUAZHE INTERNATIONAL TRADE CO., LTD.
SUITE 602, CIMIC TOWER, 1090 CENTURY AVENUE, PUDONG, SHANGHAI, CHINA.
Manufacturer Code SHAMU05010
Type designation KD-737, KD-788, MW-300, KD-388, KD-525E, KD-559, KD-575
Technical data DC 3V, 2 x AAA Battery for KD-737, KD-788, MW-300
DC 6V, 4 x AA Battery for KD-388, KD-525, KD-559, KD-575

The submitted sample of the above equipment has been tested for CE marking according to the following European Directives:

- Medical Device Directive (93/42/EEC)

Standard(s) used for showing compliance with the essential requirements in the specified directive(s).

<i>Standard(s)</i>	<i>Test report(s)</i>	<i>Issued by</i>	<i>Date(s)</i>
EN 60601-1-2:2001/+A1:2004	Ref No. JSH05110154-001	Intertek Testing Services Shanghai Ltd.	November 15, 2005

The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s).

After preparation of the necessary technical documentation as well as the conformity declaration the CE marking as shown below can be affixed on the equipment. Other relevant Directives have to be observed.

NOTE: This verification is part of the full test report and should be read in conjunction with it.

Shanghai, November 15, 2005

STEVE LI
EMC MANAGER



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