Product List und Application MDD, AIMDD

TÜVRheinland®

Name Legal Manufacturer	Hangzhou Hua'an Medical & Health Instruments Co., Ltd.
Address Legal Manufacturer	Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, Hangzhou, 310023 Zhejiang, China
MDD 93/42/EEC	Annex II excluding Section 4
Reason for submission of product list	New product list

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Declaration of the applicant

I hereby apply for the assessment of my quality assurance system with respect to the product(s) listed hereafter.

I hereby declare
• that no application has been lodged with any other notified body for the same product-related quality system.

In relation to the quality assurance system I assure
• to fulfil the obligations imposed by the quality system approved;
• to keep the approved quality system adequate and efficacious;
• to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action;
• to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following incidents immediately on learning of them:
i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph i) to systematic recall of devices of the same type by the manufacturer.

Additionally I declare
• to submit to the notified body the relevant documentation on the quality assurance system and the necessary documentation on the product(s) to be evaluated ("technical documentation");
• to keep the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH for a duration of at least five years, and, in the case of implantable devices at least 15 years, after manufacture of the last product;
• that all listed devices meet the essential requirements set out in Annex I of Directive 93/42/EEC;
• to inform TÜV Rheinland LGA Products GmbH without delay in case of inquiries by any competent authority regarding the products covered by this application;
• to inform TÜV Rheinland LGA Products GmbH about any planned substantial changes to the approved quality assurance system (e. g. procedural changes regarding design and development, production, or end control), or the products/product range covered by it;
• to submit an informal application for certificate extension to the notified body, at least 6 months before expiry of the certificate. A different date may be agreed by means of a contract:

TÜV Rheinland LGA Products GmbH
Certification Office Medical
Am Grauen Stein 29
51105 Cologne
Germany
E-Mail: medical-products@de.tuv.com

As a manufacturer who does not have a registered place of business in an EU member state, (including states holding an appropriate agreement with the EC), I additionally declare,
• to designate per product one authorized representative established in the Community;
• to inform TÜV Rheinland LGA Products GmbH in case the authorized representative has changed;
• that the authorized representative keeps all relevant product documentation, including the declaration of conformity, for a duration of at least five years, and in the case of implantable devices at least 15 years, after manufacture of the last product;
• to sign an agreement with the authorized representative which clearly defines the interfaces and responsibilities, in order to comply with the current "EC Guidelines on a Medical Devices Vigilance System".

杭州华安医疗仪器有限公司 3301100...

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Code of facilities	Scope of facilities	Name of facility	Address of facility
EAR(1)	European Authorized Representative	Shanghai International Holding Corp. GmbH (Europe)	Eiffestrasse 80, 20537, Hamburg,Germany DIMDI Code: DE/0000040627
IMF(1)	Internal Manufacturing Facility	Hangzhou Hua'an Medical & Health Instruments Co., Ltd.	Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, Hangzhou, 310023 Zhejiang, China
EMF(1)	External Manufacturing Facility		
R&D(1)	Research & Development	Hangzhou Hua'an Medical & Health Instruments Co., Ltd.	Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, Hangzhou, 310023 Zhejiang, China
OEM(1)	Original Equipment Manufacturer		
Sterilization facility Radiation (1)			

Sterilization facility Gas(1)			
Sterilization facility Heat(1)			
Sterilization facility: Other sterilization methods(1)			

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Please enter product details below or use a separate controlled list which makes reference to this application (e.g. by refering to the application date)

add a new product	delete the last product	add a copy of the last line	table reset

Product name (as listed on label)	General product group name	Classification Rule including subclause according to Annex IX	Device Class	Allocation of all products into Device Subcategories [NBOG BPG 2009-3]	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only	TD/DD identifier	Choose from above code of facilities	Summary list of related facilities	Code of EU-REP [see above]
Digital thermometers model: DT-01A,DT-01B, DT-01D,DT-01E, DT-01G,DT-11A, DT-11B,DT-11D, DT-11E,DT-11G, DT-11H,DT-02,DT-12, DT-101A,DT-111A, DT-101B,DT-111B, DT-111D,DT-111G,DT-K01A,DT-K11A,DT-K11B,DT-K11E,DT-K101A,DT-K111A,DT-K111B,DT-K111D,DT-Y111D	Digital Thermometers	Rule 10, 3.2/1	IIa	MD 1301 Mon	NA	NA	HA/MF 01-2018E		IMF(1);R&D(1);	EAR(1)

Reference **Hangzhou Hua'an Medical & Health Instruments Co., Ltd. / 2018-12-13**

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Infra-red Ear Thermometers moder; ET-100A,ET-100B, ET-100D,ET-100E, ET-100G,ET-100I, ET-100J	Infra-red Ear Thermometers	Rule 10, 3.2/1	IIa	MD 1301 Mon	NA	NA	HA/MF 02-2018E		IMF(1);R&D(1);	EAR(1)
Digital Blood-pressure Monitor Model; MW-300A,MW-300B, MW-300C,MW-300D, MW-300E,MB-300A, MB-300B,MB-300C, MB-300D,MB-300H	Digital Blood Pressure Monitors (Digital Sphygmomanometers)	Rule 10, 3.2/1	IIa	MD 1301 Mon	NA	NA	HA/MF 03-2018E		IMF(1);R&D(1);	EAR(1)
Infra-red Forehead Thermometer Model; FT-100A, FT-100B,FT-100D, FT-100E	Infra-red Forehead Thermometers	Rule 10, 3.2/1	IIa	MD 1301 Mon	NA	NA	HA/MF 04-2018E		IMF(1);R&D(1);	EAR(1)

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Date 13.12.2018

Location Hangzhou

Legally binding signature

Gesehen/Reviewed
Shanghai ...2019.01.08.....
TÜV Rheinland LGA Products GmbH