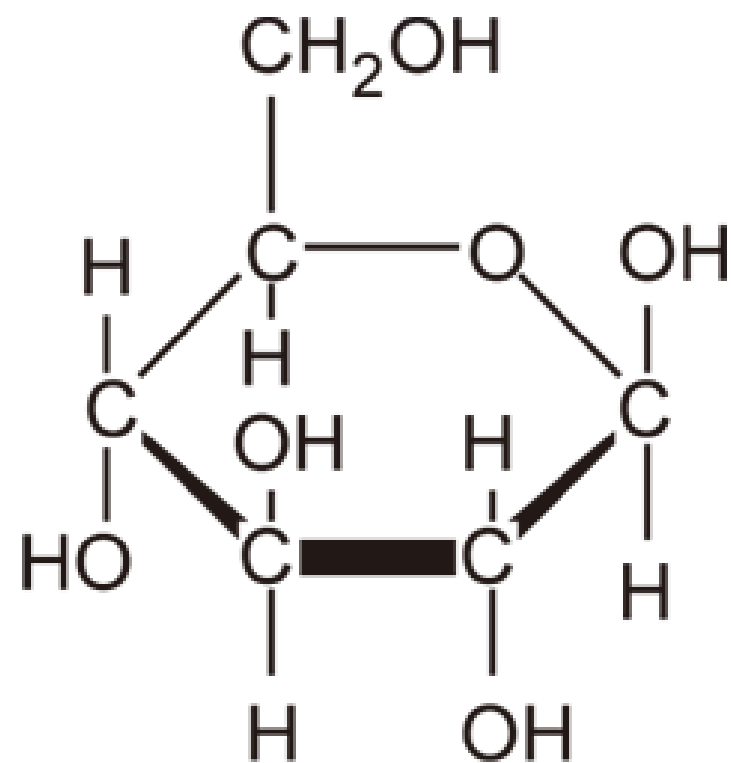




HMD Biomedical Inc.

HMD BiOMEDICAL INC.

厚美德生物科技股份有限公司



Glucose



HMD BioMEDICAL INC.

厚美德生物科技股份有限公司

- **Founded in May 2000**
- **Founder : Dr. Tim Hsu**
 - PhD in Biotechnology
Braunschweig University
of Technology.
 - 30 Years in Biosensor
research.
 - Director of BME.
- **Patents : 50+ in biosensor field**



工業技術研究院
Industrial Technology
Research Institute



中華生物醫學工程商業協進會
Chinese Business Association of
Bio-Medical Engineering



About HMD

Devoted in the manufacturing research and development of blood glucose monitoring system, HMD Biomedical is dedicated to provide safe and reliable products to help diabetes families lead a better life and improve the service quality of medical care professionals.

■ Vision

Be the leading company of diabetes cares supplies

■ Mission

Heartiness for Managing Diabetes

■ Professional

Over 30 years in the glucose biosensor research

- Quality Assurance Policy
- Response to customer's claims positively
- Keep improving product & service quality actively
- Dedicate in research & development
- Create the company value via Innovation



History

- **2021.05 OEM Rapid Test Reagent Products**
- **2017.09 First MDSAP Certified Medical Device Manufacturer in Taiwan**
- **2015.03 Signed Parcerias de Desenvolvimento de Produtos (PDP's) with Brazil government**
- **2015.02 China Factory Opening, for China market demand**
- 2014.01 GSM Claudia G2 FDA510(k) cleared
- **2013.09 Brazil ANVISA certified**
- 2012.07 AC300 FDA510(k) cleared
- **2010.04 Taiwan Second Factory Opening, Production Expanded for growing demand**
- **2010.01 Partnership with CGM to supply POCT product**
- 2008.12 SFDA certified
- 2005.09 US CAP certified
- 2005.09 FDA 21CFR.820 QSR
- 2005.05 GMP certified
- 2002.09 IVDD 98/79/EC certified
- 2002.09 ISO9001 & ISO13485 certified
- **2000.05 Founded in Hsinchu,Taiwan**



MDSAP certificate

CERTIFICATE
No. QS6 17 08 97447 002

Certificate Holder: HMD BioMedical Inc.
No.181, Minsheng Street
30548 Xintu Township, Hsinchu County
TAIWAN

Certification Mark:  

Scope of Certificate: Design and Development, Production, and Sales of Blood Glucose Monitoring System (Including Blood Glucose Meter, Blood Glucose Test Strip, and Glucose Control Solution) for the Measurement of Blood Sugar

Standard(s): ISO 13485:2003

Regulatory Authority: ANVISA/FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

DUNS No: 65-864-4174
Effective Date: 2017-08-11
Expiry Date: 2019-02-28


Earl Buckmiller
Director, Quality Systems & MS Cert. Body



Page 1 of 2

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com TÜV

CERTIFICATE
No. QS6 17 08 97447 002

Audit/Certification Criteria


Brazil

- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Effective Date: 2017-08-11
Expiry Date: 2019-02-28


Earl Buckmiller
Director, Quality Systems & MS Cert. Body

Page 2 of 2

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com TÜV

Certificates-ISO/CE

CERTIFICATE
No. Q5 18 02 97447 003

Holder of Certificate: HMD BioMedical Inc.
No. 181, Minsheng Street
30548 Xipu Township, Hainchu County
TAIWAN

Certification Mark:  

Scope of Certificate: Design and Development, Production, and Sales of Blood Glucose Monitoring Systems (Including Blood Glucose Meter, Blood Glucose Test Strip, and Glucose Control Solution) for the Measurement of Blood Sugar

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: TW1803504

Valid from: 2018-07-01
Valid until: 2021-06-30

Date: 2018-05-23
Stefan Prell
Stefan Prell

Page 1 of 2

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridlerstraße 65 - 80339 München - Germany

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV
excluding (4, 6)
(List A and B and devices for self-testing)
No. V1 18 02 97447 004

Manufacturer: HMD BioMedical Inc.
No. 181, Minsheng Street
30548 Xipu Township, Hainchu County
TAIWAN

Facility(ies): HMD BioMedical Inc.
No. 181, Minsheng Street, 30548 Xipu Township, Hainchu County, TAIWAN

Product Category(ies): Blood glucose measuring systems for self testing
(Blood glucose test devices for self-testing)

Model(s): Self-Monitoring Blood Glucose system GlucoLeader Enhance
Blood Glucose Meter GlucoLeader Enhance
Blood Glucose Test Strip GlucoLeader Enhance
Glucose Control Solution GlucoLeader Enhance
Self-Monitoring Blood Glucose system GlucoLeader Enhance 2
Blood Glucose Meter GlucoLeader Enhance 2
Blood Glucose Test Strip GlucoLeader Enhance 2
Glucose Control Solution GlucoLeader Enhance 2
Self-Monitoring Blood Glucose system GL GoodLife 801
Blood Glucose Meter GL GoodLife 801
Blood Glucose Test Strip GL GoodLife 801
Glucose Control Solution GL GoodLife 801

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (A) certificate is mandatory. See also notes overleaf.

Report no.: TW1803504

Valid from: 2018-07-01
Valid until: 2019-06-30

Date: 2018-05-24
Stefan Prell
Stefan Prell

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridlerstraße 65 - 80339 München - Germany

GMP Quality System Certificate

MINISTRY OF HEALTH AND WELFARE
REPUBLIC OF CHINA (TAIWAN)

Issue Date: February 4, 2020 No: MN001043
GMP Certificate

Name of Manufacturer : HMD BIOMEDICAL INC.
Address of Manufacturer : NO. 181, MINSHENG ST., XINPU TOWNSHIP,
HSINCHU COUNTY, TAIWAN (R.O.C.)

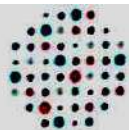
GMP Registration Number : GMP0797
Expiry Date : February 8, 2023
Scope of Registration : 1. Glucose Test System-Blood Glucose Meter, 2.
Glucose Test System-Blood Glucose Test Strip, 3.
Quality Control Material (Assayed and
Unassayed)-Control Solution.

The above-mentioned manufacturer has been inspected periodically by the
Ministry of Health and Welfare and found to be in compliance with the
medical device Good Manufacturing Practice (GMP) requirements (based on
ISO 13485). This certificate is hereby issued pursuant to Paragraph 3,
Article 57 of the Pharmaceutical Affairs Act.
This certificate may not be used as a product license.

Signed by *Shou-Mei Wu*
Director General
Food and Drug Administration
Under the delegated authority of
Shih-Chung Chen, D.D.S., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

MN 001043

CAP certificate



COLLEGE of AMERICAN
PATHOLOGISTS

CERTIFICATE OF PARTICIPATION

2021 Proficiency Testing/External Quality Assurance

**HMD Biomedical Inc
R & D**

CAP Number: 7191504-01


This certificate recognizes your participation in the College of American Pathologists' Proficiency Testing and/or Anatomic Pathology Education Programs for the 2021 program year.

Bradley S. Karon, MD, PhD, FCAP
Chair, Council on Scientific Affairs

Emily E. Volk, MD, FCAP
President, College of American Pathologists

EN ISO 15197:2015 Certificate

- The International Organization for Standardization of Glucose Monitoring System
- Glucose result is < 100 mg/dL, the error should be less than 15 mg/dL
- Glucose result is ≥ 100 mg/dL, the error should be less than 15%.
- More than 95% of the results meet the acceptance criteria



CERTIFICATE
of Conformity

Registration No.: AK 50377117 0001
Report No.: 50073575 001

Holder: HMD BioMedical Inc.
No. 181, Minsheng St.,
Xinpu Township, Hsinchu County 305
Taiwan, R.O.C.

Product: Analysis Equipment
(Blood Glucose Monitoring System)

Identification: GlucoLeader Enhance; GlucoLeader Enhance 2

Remark: The scope of this evaluation covers only clause 6.3 of EN ISO 15197:2015 (ISO 15197:2013). All other requirements and aspects are excluded. This certificate is based on a review of the results provided in the Reports No.: 2015/11/02, dated 2016-01-04.

Tested acc. to: ISO 15197:2013
EN ISO 15197:2015

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

Date: 09.05.2017

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

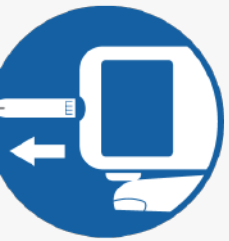
Dipl.-Ing. W. Hsu

Blood Glucose Test

FDA CE 0123



POC for Hospital Bedside service



- US FDA: k113314
- CAP code :1882
- Total Quality Control
- **Build-in Barcode scanner**
 - Multi-IDs (PID/UID/Strip/GCS)
 - No human input error
- **GDH-FAD enzyme**
- **Precision & Accuracy**
 - Small sample size (0.5uL)
- **Easy Operation**
- **Design for Medical**
 - Strip ejector
 - Long-handled strip
- **Auto QC report**
 - Simple and fast treatment
 - Auto-lock



Blood Glucose Meter

GV 01 Blood Glucose Monitoring System

- Accuracy fully compliant with ISO 15197:2013
- Accurate results in less than 5 seconds.
- Unique AC, PC setting.
- 800 test memory with date and time.
- Memory recall function.
- Power saving, automatic shut-off in 3 minutes.
- Made in Taiwan













Enhance Blood Glucose Monitoring System

- Accuracy fully compliant with ISO 15197:2013
- Accurate results in less than 5 seconds.
- Unique AC, PC setting.
- 800 test memory with date and time.
- Memory recall function.
- 7, 14, 21, 28 days average display.
- Power saving, automatic shut-off in 3 minutes.
- Made in Taiwan



IoT connectivity

BGM	Mechine-to-Mechine M2M solutions	Features
Enhance 	Bluetooth Low Energy BLE 	<ul style="list-style-type: none"> • CE / FDA certified • Event Alarm Setting • HCT 0-70%
AC-300 	Near Field Communication NFC 	<ul style="list-style-type: none"> • FDA cleared • Multi-users, P15 • 1 battery, CR2032
G2 	GSM 	<ul style="list-style-type: none"> • FDA cleared • Multi-users, P15 • Background uploading • 4 AAA batteries
NS-101 	IR Barcode scanner + USB/Wifi   	<ul style="list-style-type: none"> • FDA cleared • CAP certified • POCT protocol and QC auto-lock • Rechargeable Li-ion battery

Blood Glucose Strip



Foil Package Strips

- Affordable & clean pack
- Humidity-free
- Longer duration of life, up to 24 months
- Good for Pharmacy retail single test service
- Reduce the risk of healthcare infection

$$\frac{\text{Beyond Use Date (BUD.)}}{\text{Expiration Date (EXP.)}} = 1$$



Vial Packet Strips

- Easy open vial.
- Long strip size, convenient to handling.
- Two sides aperture, free to apply blood sample from either side of strip.



.....Alternative

to apply blood sample from either side of the test strip.



Diabetic supplies

Therapeutic Socks for Diabetic

- Anti-bacteria
- Far-Infrared Ray
- Dry & Ventilate



Dr. Free™ is a high-performance fiber with the function of anti-bacteria, the fiber with nano powders in polymer can reduce the risk of germs growth. In addition, the nano-powders of Far Infrared Ray and Minus Ions in fiber material can keep the body warm, healthy and comfortable feeling.

NanoRed releases the energy of Far-IR to improve blood circulation. Meanwhile the fabric can also provide the function of Minus Ions, which can relax nervous emotion to keep healthy.

CoolBest is a fiber with the function of specific "cross (+) section" for speeding sweat away from skin to the outer surface of fabric to make skin feel dry, refreshing and comfortable.



Blood Glucose System Accessories

Lancing Device

- Depth indicator
- Pain-free : Interference fit between lancet and sleeve reduce the waggle of the lancet.
- Ejectable
- Well-designed appearance bring you comfortable operation experience



Twist Lancet

- Fine gauge,
- tri-bevel tip for virtually painless sampling.
- Consistent depth penetration.
- Universal lancet that fits most of lancing devices.

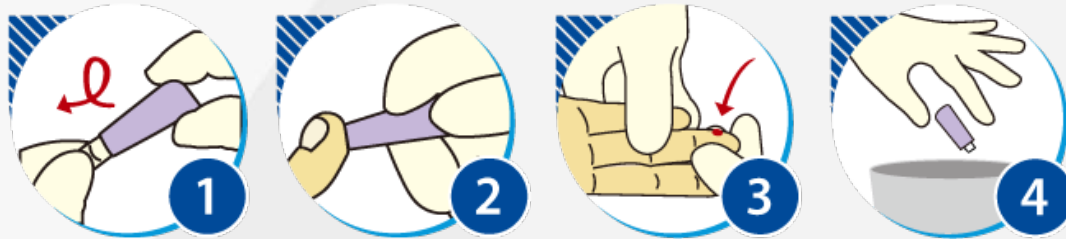


Infection Control Supplies



Safety lancet

- Quick and Safe
- Auto-disable while launched
- Prevent the healthcare infections



Antimicrobial Copper Fabric



Nano Cupric Ion Medical Mask (Non-Sterile)

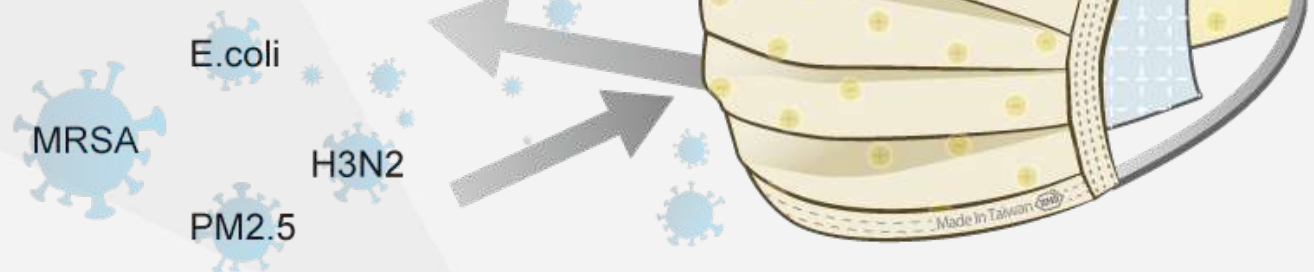
- Approval with EN 14683: 2019 With high bacterial filtration efficiency and high air permeability
- BFE Bacterial Filtration Efficiency >99.5%



Inner Layer :
Hydrophilic Nano Cupric Ion Non-woven fabric

Middle Layer :
Melt-blown Non-woven fabric

Outer Layer :
Water repellent Nano Cupric Ion Non-woven fabric



Antimicrobial Copper Fabric



Antimicrobial Copper Mask



- **High performance filter and like charges repel effect**
 - Free of PM2.5 dust and germ, 99%
 - Excellent PM2.5/germ barrier and air respiration
 - Tested by Intertek and TTRI
- **Sustainable nano-composites microbialcide material**
 - Continuous anti-microbial activity
- **Natural material and color**
 - Earth and skin friendly
 - Copper is an essential trace element of human body
- **High UV protection performance**
 - Enjoy the sun safely

Antibacterial Copper Fabric



Copper Socks

- Anti-microbial
- Odor control
- Ventilated
- Keep warm
- Personal hygiene



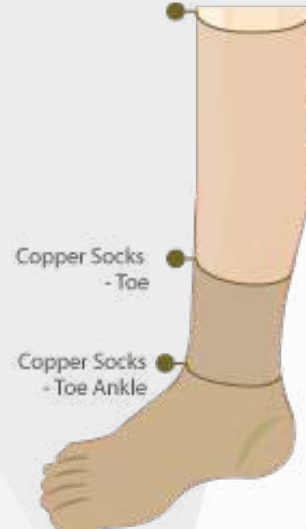
Copper Socks
Toe Ankle



Copper Socks
Toe



Copper Socks
Toe Knee



Copper Socks
- Toe

Copper Socks
- Toe Ankle



Copper Socks
Low Socks



Copper Socks
Quarter Socks



Copper Socks
Crew Socks



Crew Socks

Quarter Socks

Low Socks

Rapid Test Reagent Products OEM

■ Professional OEM services :

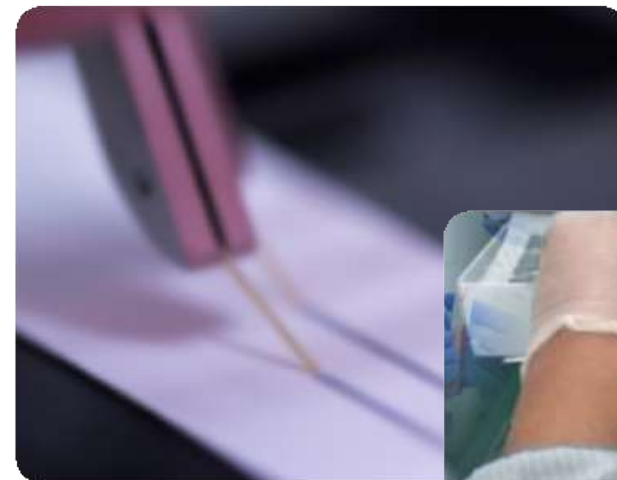
Our custom OEM service can save you additional resources such as equipment and personnel training, as well as the cumbersome manufacturing process when you invest yourself, allowing you to focus more on research design and experiments Analysis, market access deployment, and clinical trial forensics.

■ We provide OEM mass production services for rapid test reagent products:

OEM manufacturing of test reagent kits

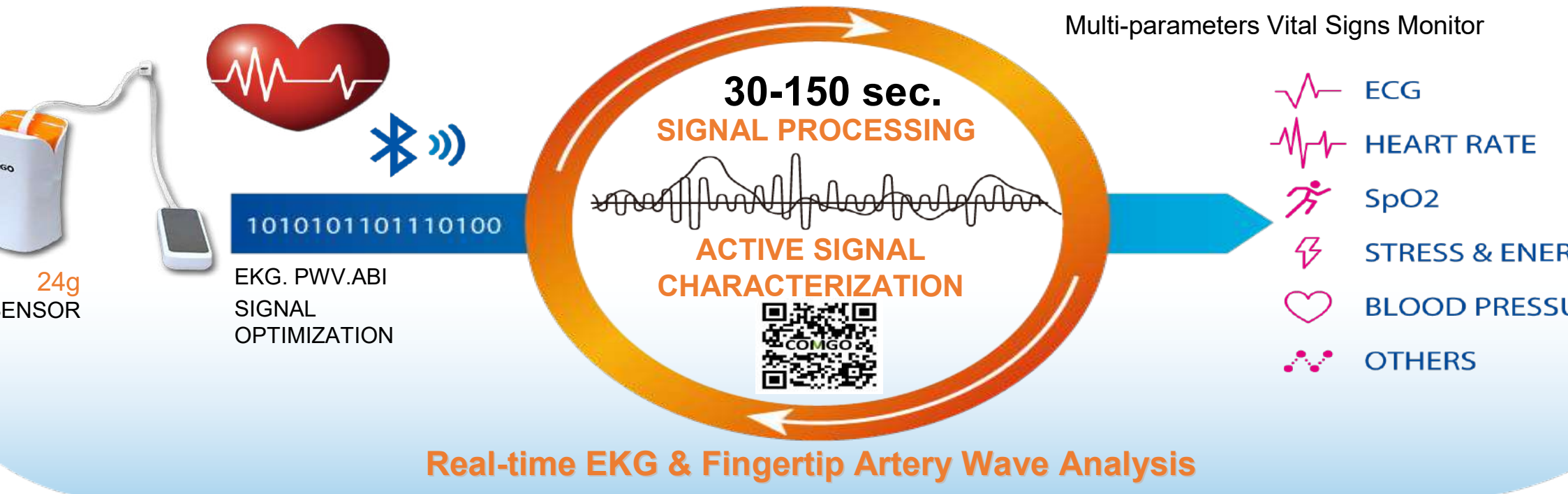
OEM manufacturing of rapid test reagents

OEM manufacturing of nucleic acid rapid test strips



COMGO

Multi-parameters Vital Signs Monitor



- Peripheral Artery Examination
 - Arteries Fatigue Analysis
 - Vascular Age Screening

- Irregular Heart Rhythm Notification
 - Blood Vessel Elasticity Test
 - Blood Thickness Test

Cardiovascular and **Mental** Health AI Assessment & Trend Report



Worldwide Distribution-

More than 45 countries





Thank you!

www.hmdbio.com

sales@hmbio.com