GIMA
PROFESSIONAL MEDICAL PRODUCTS

# *Sfigmomanometro elettronico*
# *Electronic Sphygmomanometer*
# *Sphygmomanomètre électronique*
# *Esfigmomanómetro Electrónico*
# *Esfigmomanómetro eletrónico*
# *Elektronisches Sphygmomanometer*
# *Sfigmomanometr elektroniczny*
# *Sfigmotensiometru electronic*
# *Ηλεκτρονικό Πιεσόμετρο*
# *Elektronický sfygmomanometr*
# *Elektronički sfigmomanometar*
# *Elektronski sfigmomanometer*
# *Elektronický tlakomer*
# *Elektronikus vérnyomásmérő*
# مقياس ضغط الدم الإلكتروني

**Gima 32797**


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Wenzhou, Zhejiang China
Made in China


REF **BK1018**


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CE 0344

IP21 MD 55°C -20°C

M32797-M-Rev.1-11.24

ENGLISH

**IMPORTANT SAFETY INSTRUCTIONS**
Prior to utilizing this instrument, please ensure that you have read both the "Instruction Manual" and "IMPORTANT SAFETY INSTRUCTIONS" thoroughly to ensure proper usage. The safety precautions outlined in this section have been provided to guide you towards the correct utilization of this instrument and prevent any harm or injury to yourself or others. It is imperative that you adhere to all of the instructions and information provided in order to maintain safety.

- Intended use: measurement of human body blood pressure.
- As per the electric shock protection type: INTERNALLY POWERED EQUIPMENT.
- According to the degree of protection against electric shock: TYPE BF APPLIED PART.
- In terms of protection against water ingress: **IP21**.
- Mode of operation: CONTINUOUS OPERATION.
- It is imperative that the device is kept in a dry environment.
- Ensure that batteries are kept out of reach of children. In the event of accidental ingestion, please seek immediate medical attention.
- This instruction manual does not contain any technical documents, including circuit diagrams, component lists, or calibration. Customers must consult the manufacturer if such documents are required.
- The usage of this device is not harmful, causes no irritation, and will not result in any allergic reactions.
- This device cannot replace a doctor's diagnosis.
  - The device has a lifespan of three years.
  -When the power is low, replace the batteries promptly. Otherwise it may cause inaccurate measurement results.
  -If any serious incident happened, the users or patients shall report it to the manufacturer and the competent authority.

**GENERAL INFORMATION**
**Product name: Electronic Sphygmomanometer**
**Intended purpose: The Electronic Sphygmomanometer is intended used to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.**
**Indication: Intermittent measurement of human body blood pressure from upper arm.**
**Intended patient population: Adults.**
**Intended users: Professional medical staff, lay persons.**

**Contraindications:**
- The product can not be used for patients with arrhythmia.
- This product can not be used for infants, neonates or pregnancy.
- People who can not express himself can not use this product.

Clinical benefits: Measuring body blood pressure so as to help to diagnose human body conditions.
Intended use environment: Medical institute, home environment.
Shelf life: 3 years

**SPECIFICATIONS**

| | |
|---|---|
| Unit | mmHg/kPa |
| Display mode | LED column and Digit LED display |
| Measurement mode | stethoscopy |
| Measurement range | Pressure: (0～300) mmHg (0～40) kPa<br>Pulse rate: (30～200) beats/minute |
| Minimal scale | LED column: 2mmHg (0.26kPa);<br>Numerical display: 1mmHg (0.13kPa) |
| Accuracy | Pressure: ±3mmHg（±0.4kPa）<br>Pulse rate: within ±5% |
| Pressurization mode | Manual operation |
| Discharging mode | Manual operation by air releasing valve |
| Over pressure warning | When pressure is more than 315mmHg(42kPa),<br>top of LED column flashes |
| power | DC4.5V; AA-size alkaline batteriesX3 |
| Operating condition | Temperature: 10℃~40℃ |
| Storage & transportation condition | Temperature: -20℃~55℃ |
| Air pressure | 500hPa-1060hPa |
| weight | Approx.584g(without cuff and battery) |
| Cuff size | 480mmX145mm |
| Suitable for arm circumference | 220mm~320mm |
| Protection against electric shock | Internally powered equipment. Type BF applied part. |
| Attachment | Cuff, inflation bulb, instruction manual |

**Operation**
Open the upper cover of the machine and connect the short tube to the air intake hole located on the top of the battery box. Then, connect the other end of the tube to the bladder of the cuff. Put the batteries into the battery compartment. To begin using the machine, press the power switch ON/OFF and it will start working immediately without any waiting time.
The machine can display readings in either mmHg or KPA. When the machine is turned on, it displays readings in mmHg. To change it to KPA, press and hold the power switch for 3 seconds.
The machine has a background light. To conserve power, the light will automatically shut off if the pressure falls below 20mmHg and remains so for more than 5 minutes when using internal power supply. However, if the pressure remains above 20mmHg, the light will not shut off and will remain on until the power is switched off. If you need to delay the shut-off by 5 minutes, you should inflate the cuff to over 20mmHg and it will remain on for another 5 minutes.
The machine can also be used with external power supply through the USB port. In this case, the automatic shut-off function is disabled for both the background light and the machine.
The machine has two displays: an LED column and a numerical display. The LED column displays readings from 0 to 300mmHg (0-40kPa). When the pressure exceeds 315mmHg (42kPa), the top of the LED column will flash. In this case, the machine should be switched off, all air should be released from the cuff, and the machine should be restarted.
The numerical display shows a power signature "[ ]", mmHg or KPA. If the "[ ]" is displayed, it indicates that the battery needs to be replaced.

**Measure instruction**
1. Before taking a blood pressure reading, it is important to relax for approximately 10-15 minutes and remain quiet and calm.
2. When measuring, ensure that the LED horizontal stripe (—) and numerical display window (o) are both zeroed and stable.
3. It is common practice to measure blood pressure on the right arm. To do so, remove any clothing that may obstruct the upper arm, and wrap the cuff around the arm evenly- ensuring that it is positioned 2-3cm higher than the humerus. The tightness of the cuff should be appropriate, with one or two fingers' space between the cuff and arm. After placing the stethoscope on the elbow artery, charge the air in the bulb until it reaches 150mmHg-220mmHg (20-30kPa). Once the desired pressure is achieved, slowly release the air by loosening the air valve on the bulb. As the pressure drops, listen for the first clear pulse sound- this value will provide your systolic pressure reading. Continue to release the air until the pulse sound disappears or changes, which will give you your diastolic pressure reading. If pressure drops below 20mmHg (2.6KPA), the pulse rate will be shown on the numerical display window. It is important to deflate the cuff at a rate of 4-5mmHg/second for an accurate pulse rate.
4. If you are unsure about the accuracy of your blood pressure reading, it is recommended to rest for 10-15 minutes and take another reading. If the blood pressure value is too high or low, it is abnormal, and seeking the advice of a medical professional for further examination is recommended.

**General knowledge for blood pressure**
With the prevalence of knowledge about medical and health care, sphygmomanometer has entered into thousands of families. Measuring blood pressure often will play a positive role on prevention of heart illness, head illness and blood vessel illness.
● Blood pressure
When blood flows in blood vessel, the pressure on blood vessel wall is called blood pressure. The blood pressure, which is generally called, is artery blood pressure. It is the power of pushing blood flowing in blood vessel.
Systolic pressure: When the blood flows from heart into artery, pressure inside artery is highest which is called systolic pressure.(Also be called high pressure.)
Diastolic pressure: When heart expands, because of the elasticity of blood vessel wall, blood remains to flow forwards. But the blood pressure will drop. The pressure is called diastolic pressure.(Also be called low pressure.)
Pulse pressure: Margin pressure between systolic pressure and diastolic pressure is called pulse pressure.
●The normal value of blood pressure and Clinical advice on variation
The systolic pressure for healthy adult is between 90-140mmHg(12-18kPa) and diastolic pressure is between 60-90mmHg(8-12kPa). The pulse pressure is between 30-40mmHg(4-5.3kPa).
The average blood pressure of children can be calculated as :agex2+80=systolic pressure(mmHg).2/3 of the systolic pressure is diastolic pressure.

The blood pressure rises with age. After 40 years old, if the age increases by 10 years old, systolic pressure will go up by 10mmHg(1.3kPa) whereas diastolic pressure is unchanged. The discrepancy between two arm's blood pressure value by 5-10mmHg(0.67-1.3kPa) margin is normal, In the condition of physiology, blood pressure is lower in the morning while it is higher in the evening, just after sports or finishing eating. The blood pressure drops slightly in hot environment whereas it raises a litter in cold environment. Moreover, being nervous, being excited,drinking alcoholic beverages and smoking will make blood pressure rise.

**Hypertension**
If systolic pressure is equal to or over 160mmHg(21.3kPa)and diastolic pressure is 95mmHg (12.6kPa), it can be defined as Hypertension.(If one of the above is verified ,it is diagnosed as Hypertension.)
Critical Hypertension
The diastolic pressure is over 90mmHg (12kPa) below 95mmHg(12.6kPa) or systolic pressure i over 140mmHg(18.6kPa) below 160mmHg (21.3kPa), both of which are defined as Critical Hypertension. According to the past standard, Critical Hypertension remains Hypertension.

**Maintenance and notice**
- When charging, ensure that the pressure does not exceed 320mmHg (42kPa).
- Please take care not to damage the surface, bulb, and bladder with sharp-edged tools.
- Avoid placing the machine in direct sunlight, damp, dusty, or corrosive gas environments.
- When closing the case of the sphygmomanometer, please put the bulb and air release valve in the highest position of the case to prevent deformation.
- Clean the machine with a cotton cloth dipped in water or neutral detergent, followed by a dry cloth. Do not use naphtha, gas, or similar diluent for cleaning.
- If not using for an extended period, remove the battery to prevent leaks or malfunctions.
- Failure to follow the instructions and correct operation methods means that our company will not be held accountable for any related quality issues.

**Appendix: EMC Standard information.**
Warning: BK1018 should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, BK1018 should be observed to verify normal operation in the configuration in which it will be used.
BK1018 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user manual; BK1018 in use may be susceptible to electromagnetic interference from portable and mobile RF communications such as mobile (cellular) telephones.

**1.1 Guidance and Manufacturer's Declarations- Electromagnetic Emissions**
BK1018 is intended for use in the electromagnetic environment specified below. The customer or user of BK1018 should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|---|---|---|
| RF Emissions<br>CISPR 11 | Group 1 | BK1018 uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions<br>CISPR 11 | Class B | BK1018 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics Emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage Fluctuations/<br>Flicker Emissions<br>IEC 61000-3-3 | Not applicable | |

**1.2 Guidance and Manufacturer's Declarations- Electromagnetic immunity**
BK1018 is intended for use in the electromagnetic environment specified below. The customer or the user of BK1018 should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment- Guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 8 kV air | Floors should be wood, Concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital Environment. |

BK1018 is not specified for use only in a shielded location and not a life-supporting device. The conducted RF and radiated RF testing is based on the standard below.

| Immunity Test | IEC 60601 Test Level | Compliance Level |
|---|---|---|
| Conducted RF<br>IEC 61000-4-6<br>Radiated RF<br>IEC 61000-4-3 | 3 V(rms)<br>150 kHz to 80 MHz<br>3 V/m<br>80 MHz to 2.5GHz | 3 V(rms)<br><br>3 V/m |

***Disposal:*** *The product must not be disposed of along with other domestic waste.*
*The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies.

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|---|---|
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| | **IT** - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB** - Caution: read instructions (warnings) carefully **FR** - Attention: lisez attentivement les instructions (avertissements) **ES** - Precaución: lea las instrucciones (advertencias) cuidadosamente **PT** - Cuidado: leia as instruções (avisos) cuidadosamente **DE** - Achtung: Anweisungen (Warnungen) sorgfältig lesen **PL** - Ostrzeżenie - Zobacz instrukcję obsługi **RO** - Atenție: Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare **GR** - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις) **CZ** - Pozor: Pečlivě si přečtěte a dodržujte pokyny (varování) k použití **HR** - Pozor: Pročitajte i pažljivo slijedite upute (upozorenja) za uporabu **SI** - Pozor: Preberite in skrbno sledite navodilom (opozorilom) za uporabo **SK** - Pozor: Pozorne si prečítajte a dodržiavajte pokyny na použitie (výstrahy) **HU** - Figyelem: Figyelmesen olvassa el és kövesse a használati utasításokat (figyelmeztetéseket)<br>**SA** - انتبه: قراءة التعليمات (التحذيرات) بعناية |
| | **IT** - Rappresentante autorizzato nella Comunità europea **GB** - Authorized representative in the European community **FR** - Représentant autorisé dans la Communauté européenne **ES** - Representante autorizado en la Comunidad Europea **PT** - Representante autorizado na União Europeia **DE** - Autorisierter Vertreter in der EG **PL** - Upoważniony przedstawiciel we Wspólnocie Europejskiej **RO** - Reprezentant autorizat pe teritoriul Comunității Europene **GR** - Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση **CZ** - Zplnomocněný zástupce v Evropském společenství **HR** - Ovlašteni predstavnik u Europskoj zajednici **SI** - Pooblaščeni zastopnik za Evropsko skupnost **SK** - Splnomocnený zástupca v Európskom spoločenstve **HU** - Meghatalmazott képviselő az Európai Közösségben<br>**SA** - ممثل معتمد في الاتحاد الأوروبي |
| | **IT** - Numero di serie **GB** - Serial number **FR** - Numéro de série **ES** - Número de serie **PT** - Número de série **DE** - Seriennummer **PL** - Numer seryjny **RO** - Număr de serie **GR** - Σειριακός αριθμός **CZ** - Sériové číslo **HR** - Serijski broj **SI** - Serijska številka **SK** - Číslo série **HU** - Sorozatszám<br>**SA** - الرقم التسلسلي |
| | **IT** - Dispositivo medico **GB** - Medical Device **FR** - Dispositif médical **ES** - Producto sanitario **PT** - Dispositivo médico **DE** - Medizinprodukt **PL** - Wyrób medyczny **RO** - Dispozitiv medical **GR** - Ιατροτεχνολογικό προϊόν **CZ** - Zdravotnický prostředek **HR** - Medicinski uređaj **SI** - Medicinski pripomoček **SK** - Zdravotnícka pomôcka **HU** - Orvostechnikai eszköz<br>**SA** - جهاز طبي |
| **IP21** | **IT** - Grado di protezione dell'involucro **GB** - Covering Protection rate **FR** - Degré de protection de l'enveloppe **ES** - Tasa de protección de cobertura **PT** - Grau de proteção do invólucro **DE** - Deckungsschutzrate **PL** - Stopień ochrony obudowy **RO** - Grad de protecție asigurat prin carcasă **GR** - Δείκτης στεγανότητας **CZ** - Stupeň krytí **HR** - Stupanj zaštite kućišta **SI** - Stopnja zaščite ohišja **SK** - Stupeň krytia **HU** - A csomagolás védelmi szintje<br>**SA** - مؤشر الحماية |
| | **IT** - Smaltimento RAEE **GB** - WEEE disposal **FR** - Disposition DEEE **ES** - Disposición WEEE **PT** - Disposição RÉEE **DE** - Beseitigung WEEE **PL** - Oddzielna zbiórka dla tego urządzenia **RO** - Eliminare DEEE **GR** - Διάθεση WEEE **CZ** - Likvidace OEEZ **HR** - Zbrinjavanje OEEO-a **SI** - Odstranjevanje OEEO **SK** - Likvidácia podľa OEEZ **HU** - RAEE szerinti ártalmatlanítás<br>**SA** - النفايات WEEE |
| | **IT** - Importato da **GB** - Imported by **FR** - Importé par **ES** - Importado por **PT** - Importado por **DE** - Eingeführt von **PL** - Importowane przez **RO** - Importat de **GR** - Εισαγωγή από **CZ** - Dovezeno uživatelem **HR** - Uvezeno od strane **SI** - Uvozil **SK** - Dovážal **HU** - Importáltat<br>**SA** - مستورد من طرف |
| | **IT** - Limite di temperatura **GB** - Temperature limit **FR** - Limite de température **ES** - Límite de temperatura **PT** - Limite de temperatura **DE** - Temperaturgrenzwert **PL** - Granica temperatury **RO** - Limită de temperatură **GR** - Όριο θερμοκρασίας **CZ** - Uchovávejte při teplotě mezi a °C **HR** - Čuvati između i °C **SI** - Hranite pri temperaturi med in °C **SK** - Uchovávajte pri teplote od do °C **HU** - És °C között tárolandó<br>**SA** - حد درجة الحرارة |
| UDI | **IT** - Identificatore univoco del dispositivo **GB** - Unique device identifier **FR** - Identifiant unique de l'appareil **ES** - Identificador de dispositivo único **PT** - Identificador exclusivo do dispositivo **DE** - Unique Device Identifier (Eindeutige Kennung des Geräts) **PL** - Unikalny identyfikator urządzenia **RO** - Identificatorul unic al dispozitivului **GR** - Unique Device Identifier (Ειδικό αναγνωριστικό συσκευής) **CZ** - Jedinečný identifikátor zařízení **HR** - Jedinstveni identifikator uređaja **SI** - Enolični identifikator naprave **SK** - Jedinečný identifikátor zariadenia **HU** - Az eszköz egyedi azonosítója<br>**SA** - معرف فريد للجهاز |
| LOT | **IT** - Numero di lotto **GB** - Lot number **FR** - Numéro de lot **ES** - Número de lote **PT** - Número de lote **DE** - Chargennummer **PL** - Kod partii **RO** - Număr de lot **GR** - Αριθμός παρτίδας **CZ** - Číslo šarže **HR** - Broj serije **SI** - Številka partije **SK** - Číslo šarže **HU** - Tételszám<br>**SA** - رقم الدفعة |
| REF | **IT** - Codice prodotto **GB** - Product code **FR** - Code produit **ES** - Código producto **PT** - Código produto **DE** - Erzeugniscode **PL** - Numer katalogowy **RO** - Cod produs **GR** - Κωδικός προϊόντος **CZ** - Kód výrobku **HR** - Šifra proizvoda **SI** - Koda izdelka **SK** - Kód výrobku **HU** - Termékkód<br>**SA** - كود المنتج |
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| | **IT** - Conservare al riparo dalla luce solare **GB** - Keep away from sunlight **FR** - À conserver à l'abri de la lumière du soleil **ES** - Conservar al amparo de la luz solar **PT** - Guardar ao abrigo da luz solar **DE** - Vor Sonneneinstrahlung geschützt lagern **PL** - Przechowywać z dala od światła słonecznego **RO** - A se păstra ferit de razele soarelui **GR** - Κρατήστε το μακριά από πλακιά ακτινοβολία **CZ** - Skladujte mimo přímé sluneční světlo **HR** - Čuvati zaštićeno od sunčeve svjetlosti **SI** - Hraniti zaščiteno pred sončno svetlobo **SK** - Skladujte mimo slnečného svetla **HU** - Napfénytől védve tárolandó<br>**SA** - يحفظ بعيدًا عن ضوء الشمس |
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| | **IT** - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB** - Caution: read instructions (warnings) carefully **FR** - Attention: lisez attentivement les instructions (avertissements) **ES** - Precaución: lea las instrucciones (advertencias) cuidadosamente **PT** - Cuidado: leia as instruções (avisos) cuidadosamente **DE** - Achtung: Anweisungen (Warnungen) sorgfältig lesen **PL** - Ostrzeżenie - Zobacz instrukcję obsługi **RO** - Atenție: Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare **GR** - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις) **CZ** - Pozor: Pečlivě si přečtěte a dodržujte pokyny (varování) k použití **HR** - Pozor: Pročitajte i pažljivo slijedite upute (upozorenja) za uporabu **SI** - Pozor: Preberite in skrbno sledite navodilom (opozorilom) za uporabo **SK** - Pozor: Pozorne si prečítajte a dodržiavajte pokyny na použitie (výstrahy) **HU** - Figyelem: Figyelmesen olvassa el és kövesse a használati utasításokat (figyelmeztetéseket)<br>**SA** - انتبه: قراءة التعليمات (التحذيرات) بعناية |
| | **IT** - Rappresentante autorizzato nella Comunità europea **GB** - Authorized representative in the European community **FR** - Représentant autorisé dans la Communauté européenne **ES** - Representante autorizado en la Comunidad Europea **PT** - Representante autorizado na União Europeia **DE** - Autorisierter Vertreter in der EG **PL** - Upoważniony przedstawiciel we Wspólnocie Europejskiej **RO** - |
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| | **IT** - Numero di serie **GB** - Serial number **FR** - Numéro de série **ES** - Número de serie **PT** - Número de série **DE** - Seriennummer **PL** - Numer seryjny **RO** - Număr de serie **GR** - Σειριακός αριθμός **CZ** - Sériové číslo **HR** - Serijski broj **SI** - Serijska številka **SK** - Číslo série **HU** - Sorozatszám<br>**SA** - الرقم التسلسلي |
| | **IT** - Dispositivo medico **GB** - Medical Device **FR** - Dispositif médical **ES** - Producto sanitario **PT** - Dispositivo médico **DE** - Medizinprodukt **PL** - Wyrób medyczny **RO** - Dispozitiv medical **GR** - Ιατροτεχνολογικό προϊόν **CZ** - Zdravotnický prostředek **HR** - Medicinski uređaj **SI** - Medicinski pripomoček **SK** - Zdravotnícka pomôcka **HU** - Orvostechnikai eszköz<br>**SA** - جهاز طبي |
| **IP21** | **IT** - Grado di protezione dell'involucro **GB** - Covering Protection rate **FR** - Degré de protection de l'enveloppe **ES** - Tasa de protección de cobertura **PT** - Grau de proteção do invólucro **DE** - Deckungsschutzrate **PL** - Stopień ochrony obudowy **RO** - Grad de protecție asigurat prin carcasă **GR** - Δείκτης στεγανότητας **CZ** - Stupeň krytí **HR** - Stupanj zaštite kućišta **SI** - Stopnja zaščite ohišja **SK** - Stupeň krytia **HU** - A csomagolás védelmi szintje<br>**SA** - مؤشر الحماية |
| | **IT** - Smaltimento RAEE **GB** - WEEE disposal **FR** - Disposition DEEE **ES** - Disposición WEEE **PT** - Disposição RÉEE **DE** - Beseitigung WEEE **PL** - Oddzielna zbiórka dla tego urządzenia **RO** - Eliminare DEEE **GR** - Διάθεση WEEE **CZ** - Likvidace OEEZ **HR** - Zbrinjavanje OEEO-a **SI** - Odstranjevanje OEEO **SK** - Likvidácia podľa OEEZ **HU** - RAEE szerinti ártalmatlanítás<br>**SA** - النفايات WEEE |
| | **IT** - Importato da **GB** - Imported by **FR** - Importé par **ES** - Importado por **PT** - Importado por **DE** - Eingeführt von **PL** - Importowane przez **RO** - Importat de **GR** - Εισαγωγή από **CZ** - Dovezeno uživatelem **HR** - Uvezeno od strane **SI** - Uvozil **SK** - Dovážal **HU** - Importáltat<br>**SA** - مستورد من طرف |
| | **IT** - Limite di temperatura **GB** - Temperature limit **FR** - Limite de température **ES** - Límite de temperatura **PT** - Limite de temperatura **DE** - Temperaturgrenzwert **PL** - Granica temperatury **RO** - Limită de temperatură **GR** - Όριο θερμοκρασίας **CZ** - Uchovávejte při teplotě mezi a °C **HR** - Čuvati između i °C **SI** - Hranite pri temperaturi med in °C **SK** - Uchovávajte pri teplote od do °C **HU** - És °C között tárolandó<br>**SA** - حد درجة الحرارة |
| UDI | **IT** - Identificatore univoco del dispositivo **GB** - Unique device identifier **FR** - Identifiant unique de l'appareil **ES** - Identificador de dispositivo único **PT** - Identificador exclusivo do dispositivo **DE** - Unique Device Identifier (Eindeutige Kennung des Geräts) **PL** - Unikalny identyfikator urządzenia **RO** - Identificatorul unic al dispozitivului **GR** - Unique Device Identifier (Ειδικό αναγνωριστικό συσκευής) **CZ** - Jedinečný identifikátor zařízení **HR** - Jedinstveni identifikator uređaja **SI** - Enolični identifikator naprave **SK** - Jedinečný identifikátor zariadenia **HU** - Az eszköz egyedi azonosítója<br>**SA** - معرف فريد للجهاز |
| LOT | **IT** - Numero di lotto **GB** - Lot number **FR** - Numéro de lot **ES** - Número de lote **PT** - Número de lote **DE** - Chargennummer **PL** - Kod partii **RO** - Număr de lot **GR** - Αριθμός παρτίδας **CZ** - Číslo šarže **HR** - Broj serije **SI** - Številka partije **SK** - Číslo šarže **HU** - Tételszám<br>**SA** - رقم الدفعة |
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| | **IT** - Dispositivo medico conforme al regolamento (UE) 2017/745 **GB** - Medical Device compliant with Regulation (EU) 2017/745 **FR** - Dispositif médical conforme au règlement (UE) 2017/745 **ES** - Producto sanitario conforme con el reglamento (UE) 2017/745 **PT** - Dispositivo médico em conformidade com a regulamento (UE) 2017/745 **DE** - Medizinprodukt im Sinne der Verordnung (EU) 2017/745 **GR** - Ιατρικό συσκευή συμφωνεί με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 **PL** - Wyrób medyczny zgodny z Rozporządzenie (UE) 2017/745 **CZ** - Zdravotnický prostředek v souladu s nařízením (EU) č. 2017/745 **SE** - Den medicintekniska produkten överensstämmer med förordning (EU) 2017/745 **FI** - Lääkinnällinen laite, joka vastaa asetusta (EU) 2017/745 **SI** - Medicinski pripomoček, skladen z uredbo (EU) 2017/745 **SK** - Zdravotnícka pomôcka v súlade s nariadením (EU) 2017/745 **RO** - Dispozitiv medical conform regulamentului (UE) 2017/745 **NL** - Medisch hulpmiddel in overeenstemming met verordening (EU) 2017/745 **HR** - Medicinski proizvod sukladan propisu (EU) 2017/745 **HU** - A 2017/745/EU rendeletnek megfelelő orvostechnikai eszköz **DK** - Medicinsk udstyr i overensstemmelse med forordning (EU) 2017/745 **BG** - Медицинск удстyr i overensstemmelse med forordning (EU) 2017/745 **LT** - Medicinos prietaisas, atitinkantis reglamentą (ES) 2017/745 **LV** - Medicīniska ierīce, kas atbilst Regulai (ES) 2017/745 **EE** - Määrusele (EL) 2017/745 vastav meditsiiniseade<br>**SA** - جهاز طبي يتوافق مع اللوائح (UE) 2017/745 |
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