

ENG · ENGLISH · ENGLISH

DECLARATION OF CONFORMITY (DOC)

- › **Manufacturer:** **Shenzhen Jamr Technology Co., Ltd**
2nd Floor, A-building, No.2 Guiyuan Road,
Guihua Community, Guanlan Town,
Longhua New District, Shenzhen, China
- › **Importer:** **emporia telecom GmbH + CoKG**
Industriezeile 36, 4020 Linz, Austria
- › **Website:** www.emporia.eu
- › **Brand name:** emporia
- › **Model:** emporia BPM-V10-B (B51)
- › **Item description:** Blood Pressure Monitor

TÜV SÜD Product Service GMBH (identification number: 0123),

Ridlerstraße 65, 80339 München, Germany,

has issued the following EU type examination certificate (certificate no.: G2 090084 0007 (Rev. 0));

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Directive 93/42/EEC Medical Device (MDD) & Directive 2007/47/EG

This declaration of conformity is issued under the sole responsibility of the manufacturer.

› **Harmonised EN basic and engineering standards**

EN ISO13485 (2016); MDD 93/42/EEC (2007) [amended by 2007_47_EC];

EN ISO14971 (2019); IEC 60601-1 (2012); IEC 60601-1-2 (2014); ISO 10993-1 (2018);

ISO 10993-5 (2009); ISO 10993-10 (2010); 9 IEC 80601-2-30 (2018); IEC 62366-1 (2015);

EN1041 (2008) +A1 (2013); MEDDEV2.7.1 (2016); IEC 62304 (2006) +A1 (2015); IEC 60601-1-11 (2015);

EN ISO 14155 (2011); EN ISO 15223-1 (2016); EN ISO81060-1 (2012); EN ISO 81060-2 (2014)

› **Responsible for the accuracy of this data**

Eveline Pupeter, CEO, emporia Telecom

01.04.2021, Linz, Austria



FRA · FRENCH · FRANÇAIS

DÉCLARATION DE CONFORMITÉ (DOC)

- › **Fabricant:** **Shenzhen Jamr Technology Co., Ltd**
2nd Floor, A-building, No.2 Guiyuan Road,
Guihua Community, Guanlan Town,
Longhua New District, Shenzhen, China
- › **Importateur:** **emporia telecom GmbH + CoKG**
Industriezeile 36, 4020 Linz, Austria
- › **Site Internet:** www.emporia.eu
- › **Nom de marque:** emporia
- › **Modèle:** emporia BPM-V10-B (B51)
- › **Description du produit:** Blood Pressure Monitor

TÜV SÜD Product Service GMBH (numéro d'identification: 0123),

Ridlerstraße 65, 80339 München, Germany,

a établi l'attestation d'examen « CE » de type (n° de certificat n° G2 090084 0007 (Rev.0)) suivante:

**L'objet de la déclaration décrit ci-dessus est conforme à la législation
d'harmonisation de l'Union applicable:**

Directive 93/42/EEC Medical Device (MDD) & Directive 2007/47/EG

La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

› **Normes EN techniques et fondamentales harmonisées**

EN ISO13485 (2016); MDD 93/42/EEC (2007) [amended by 2007_47_EC];

EN ISO14971 (2019); IEC 60601-1 (2012); IEC 60601-1-2 (2014); ISO 10993-1 (2018);

ISO 10993-5 (2009); ISO 10993-10 (2010); 9 IEC 80601-2-30 (2018); IEC 62366-1 (2015);

EN1041 (2008) +A1 (2013); MEDDEV2.7.1 (2016); IEC 62304 (2006) +A1 (2015); IEC 60601-1-11 (2015);

EN ISO 14155 (2011); EN ISO 15223-1 (2016); EN ISO81060-1 (2012); EN ISO 81060-2 (2014)

› **Responsable de l'exactitude des données**

Eveline Pupeter, CEO, emporia Telecom

01/04/2021, Linz, Autriche



GER · GERMAN · DEUTSCH KONFORMITÄTSERKLÄRUNG (DOC)

- › **Hersteller:** **Shenzhen Jamr Technology Co., Ltd**
2nd Floor, A-building, No.2 Guiyuan Road,
Guihua Community, Guanlan Town,
Longhua New District, Shenzhen, China
- › **Importeur:** **emporia telecom GmbH + CoKG**
Industriezeile 36, 4020 Linz, Austria
- › **Website:** www.emporia.eu
- › **Markenname:** emporia
- › **Modell:** emporia BPM-V10-B (B51)
- › **Artikelbeschreibung:** Blood Pressure Monitor

TÜV SÜD Product Service GMBH (Kennnummer: 0123),

Ridlerstraße 65, 80339 München, Germany,

hat folgende EU-Baumusterprüfbescheinigung (Zertifikat Nr.: G2 090084 0007 (Rev.0)) ausgestellt:

**Der oben beschriebene Gegenstand der Erklärung erfüllt die
einschlägigen Harmonisierungsrechtsvorschriften der Union:**

Directive 93/42/EEC Medical Device (MDD) & Directive 2007/47/EG

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.

› **Harmonisierte EN-Fach- und Grundnormen**

EN ISO13485 (2016); MDD 93/42/EEC (2007) [amended by 2007_47_EC];

EN ISO14971 (2019); IEC 60601-1 (2012); IEC 60601-1-2 (2014); ISO 10993-1 (2018);

ISO 10993-5 (2009); ISO 10993-10 (2010); 9 IEC 80601-2-30 (2018); IEC 62366-1 (2015);

EN1041 (2008) +A1 (2013); MEDDEV2.7.1 (2016); IEC 62304 (2006) +A1 (2015); IEC 60601-1-11 (2015);

EN ISO 14155 (2011); EN ISO 15223-1 (2016); EN ISO81060-1 (2012); EN ISO 81060-2 (2014)

› **Für die Richtigkeit der Angaben**

Eveline Pupeter, CEO, emporia Telecom

01.04.2021, Linz/Austria



ITA · ITALIAN · ITALIANO

DICHIARAZIONE DI CONFORMITÀ (DOC)

- › **Produttore:** **Shenzhen Jamr Technology Co., Ltd**
2nd Floor, A-building, No.2 Guiyuan Road,
Guihua Community, Guanlan Town,
Longhua New District, Shenzhen, China
- › **Importatore:** **emporia telecom GmbH + CoKG**
Industriezeile 36, 4020 Linz, Austria
- › **Sito web:** www.emporia.eu
- › **Nome della marca:** emporia
- › **Modello:** emporia BPM-V10-B (B51)
- › **Descrizione dell'articolo:** Blood Pressure Monitor

TÜV SÜD Product Service GMBH (codice identificativo: 0123),

Ridlerstraße 65, 80339 München, Germany,

ha rilasciato il seguente certificato di esame UE del tipo (n. certificato: G2 090084 0007 (Rev. 0)):

L'oggetto della dichiarazione sopra specificato soddisfa la pertinente normativa di armonizzazione dell'Unione:

Directive 93/42/EEC Medical Device (MDD) & Directive 2007/47/EG

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante.

› **Norme specifiche e norme di base EN armonizzate**

EN ISO13485 (2016); MDD 93/42/EEC (2007) [amended by 2007_47_EC];

EN ISO14971 (2019); IEC 60601-1 (2012); IEC 60601-1-2 (2014); ISO 10993-1 (2018);

ISO 10993-5 (2009); ISO 10993-10 (2010); 9 IEC 80601-2-30 (2018); IEC 62366-1 (2015);

EN1041 (2008) +A1 (2013); MEDDEV2.7.1 (2016); IEC 62304 (2006) +A1 (2015); IEC 60601-1-11 (2015);

EN ISO 14155 (2011); EN ISO 15223-1 (2016); EN ISO81060-1 (2012); EN ISO 81060-2 (2014)

› **Per l'esattezza dei dati**

Eveline Pupeter, CEO, emporia Telecom

01/04/2021, Linz/Austria



NED · DUTCH · NEDERLANDS CONFORMITEITSVERKLARING (DOC)

- › **Fabrikant:** **Shenzhen Jamr Technology Co., Ltd**
2nd Floor, A-building, No.2 Guiyuan Road,
Guihua Community, Guanlan Town,
Longhua New District, Shenzhen, China
- › **Importeur:** **emporia telecom GmbH + CoKG**
Industriezeile 36, 4020 Linz, Austria
- › **Website:** www.emporia.eu
- › **Merknaam:** emporia
- › **Model:** emporia BPM-V10-B (B51)
- › **Artikelbeschrijving:** Blood Pressure Monitor

TÜV SÜD Product Service GMBH (identificatienummer: 0123),

Ridlerstraße 65, 80339 München, Germany,

heeft het volgende EU-typekeuringscertificaat (certificaatnr.: G2 090084 0007 (Rev. 0)) afgegeven:

**Het hierboven beschreven onderwerp van de verklaring voldoet aan de
desbetreffende wettelijke harmonisatievoorschriften van de Unie:**

Directive 93/42/EEC Medical Device (MDD) & Directive 2007/47/EG

Deze conformiteitsverklaring wordt verstrekt onder volledige
verantwoordelijkheid van de fabrikant.

› **Geharmoniseerde EN-normen en basisnormen**

EN ISO13485 (2016); MDD 93/42/EEC (2007) [amended by 2007_47_EC];

EN ISO14971 (2019); IEC 60601-1 (2012); IEC 60601-1-2 (2014); ISO 10993-1 (2018);

ISO 10993-5 (2009); ISO 10993-10 (2010); 9 IEC 80601-2-30 (2018); IEC 62366-1 (2015);

EN1041 (2008) +A1 (2013); MEDDEV2.7.1 (2016); IEC 62304 (2006) +A1 (2015); IEC 60601-1-11 (2015);

EN ISO 14155 (2011); EN ISO 15223-1 (2016); EN ISO81060-1 (2012); EN ISO 81060-2 (2014)

› **Verantwoordelijk voor de juistheid van de gegevens**

Eveline Pupeter, CEO, emporia Telecom
01-04-2021, Linz/Austria

