

DECLARATION OF CONFORMITY**No. 20200310/12**

According to Directive 93/42/EEC, Annex VII and Annex IV of the Medical Device Regulation 2017/745 of EU Parliament and the Council

Manufacturer:	Honsun (Nantong) Co. Ltd.
Address:	No. 8 Tonghing road, Economic and Technological Development Area, 226009, Nantong City, China
Supplier:	ROYAX, s.r.o
Address:	Obchodní 107, Cestlice, 251 01, Czech Republic
Name of Device:	Palm Sphygmomanometer
Device Types` Codes:	R-MEI-S-01
Class of Device:	Class I (with measuring function) According to Rule 1 of the Part III (Classification) namely non-invasive device of Annex IX of the EU Community Council Directive 93/42 EEC.

ROYAX, s.r.o. hereby declares that the above specified medical device has been determined as a Class I device according to the requirements of Annex IX of the European Community Council Directive 93/42/EEC and Annex IX of the Medical Device Regulation 2017/745 of EU Parliament and the Council.

ROYAX, s.r.o. further declares that the product complies with the relevant provisions of Directive 93/42/EEC and Annexes of the Medical Device Regulation 2017/745 of EU Parliament and the Council concerning medical devices and as well as the product's conformity with the Essential Requirements in Annex I of the Directive 93/42/EEC.

The product has been designed, developed, manufactured and tested in accordance with all applicable standards mentioned below and by using a quality management system according to DIN EN ISO 13485:2016 for medical devices.

The above mentioned products have met the requirements of the medical device for placing CE marking and ISO 13485:2016 for medical devices.

The current declaration of conformity has been drafted in accordance with the requirements of the Annexes IV and V of the Medical Device Regulation 2017/745 of EU Parliament and the Council.

The conformity assessment procedure has been applied according to Annex VII of European Community Council Directive 93/42/ EEC.

Standards Applied:

ISO 81060-2:2013 - Non-invasive sphygmomanometers

EN 1041:2008 information supplied by manufacturer

EN ISO 15223:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

ROYAX, s.r.o.

Obchodní 107, 251 01 Čestlice, Czech Republic

Tel.: +420 321 123 111, Fax.: +420 321 123 112, E-mail: info@royax.eu, www.royax.eu

ID No.: 247 55 346, VAT ID No.: CZ 247 55 346

EN 14971:2012 Medical devices - Application of risk management to medical devices

In Cestlice, Czech Republic, March 10, 2020

NAME: Rambod Afrashteh

Position :CEO

SIGNATURE:



ROYAX, s.r.o.
Obchodní 107
251 01 Cestlice
IČ: 247 55 346

E: info@royax.eu
T: +420 321 123 111
www.royax.eu

ROYAX, s.r.o.

Obchodní 107, 251 01 Cestlice, Czech Republic

Tel.: +420 321 123 111, Fax.: +420 321 123 112, E-mail: info@royax.eu, www.royax.eu

ID No.: 247 55 346, VAT ID No.: CZ 247 55 346