



**FAST ČR, a.s.**

Černokostecká 1621, 251 01 Říčany, Czech Republic  
tel.: +420 323 204 111, fax: +420 323 204 110

## EU DECLARATION OF CONFORMITY

**Product/ brand:** Blood Pressure Monitor/ **SENCOR**

**Type/ model:** **SBD 1470 as factory model TMB-1117-S**  
DC 3V (2 x 1,5V „AAA“ batteries)  
CLASS IIA, RULE 10

**Manufacturer:** Guangdong Transtek Medical Electronics Co.,Ltd.,  
Zone A, No.105 ,Dongli Road ,Torch Development  
District, Zhongshan,Guangdong,China

**Distributor:** FAST ČR, a.s.  
Černokostecká 2111, 100 00 Praha 10, Czech Republic

**Notified body:** TÜV SUD Product service GMBH, Riddlerstrasse 65, D-80339 Munchen, Germany

**EC representative:** MDSS – Medical Device Safety Service GMBH,  
Schiffgraben 41, 30175 Hannover, Germany

**EC certificate:** No. G1 082800 0026 rev.01

**The product is inline with regulations listed below:**

Directive Medical Devices 93/42/EEC and 2007/47/EEC

Directive EMC 2014/30/EU

Directive RoHS 2011/65/EU

**and norms:**

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

EN 60601-1:2006+A1:2013

EN 60601-11:2015

EN ISO 81060-1:2012

EN 1060-31997+A2:2009

IEC 80601-2-30:2009+A1:2013

EN 60601-1-2:2015

EN 60601-1-6:2010+A1:2015

EN 62366-1:2015+AC:2015

EN 62304:2006+A1:2015

EN ISO 10993-1:2009

EN ISO 10993-5:2009

EN ISO 10993-10:2010

MEDDEV.2.7.1:2016

ISO 81060-2:2013



**Place of issuance:** Prague

**Name:** Ing. Zdeněk Pech  
Chairman of the Board

**Date of issuance:** 1. 4. 2020

**Signature:**

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**IČO:** 26 72 65 48, **DIČ:** CZ-26 72 65 48

**Bankovní spojení:** Komerční banka Praha 1, č.ú. 89309011/0100, Česká spořitelna Praha 4, č.ú. 2375682/0800, ČSOB Praha 1, č.ú. 8010-0116233383/0300