



## DECLARATION OF CONFORMITY

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MANUFACTURER: TensioMed Kft.  
1103 Budapest Kőér u. 2/E  
Hungary

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PRODUCT (name, name as listed on label, group, type): ABPM, **TensioDay**, blood pressure monitor, TD3

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CLASSIFICATION: Class IIa, Rule 10 according to Annex IX of the MDD

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**We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.**

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STANDARDS APPLIED: EN 980:2008  
EN 1041:2008  
EN 1060-1:1995+A2:2009  
EN 1060-3:1997+A2:2009  
EN 1060-4:2004  
MSZ EN ISO 13485:2004  
EN ISO 14971:2009  
EN 60601-1:2006  
EN 60601-1-2:2007  
EN 60601-1-6:2007  
EN 62304:2006  
EN 62366:2008  
EN ISO 10993-1:2009  
EN ISO 10993-3:2009  
EN ISO 10993-10:2009

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NOTIFIED BODY: TÜV Rheinland IterCert Kft., 1008  
H-1132 Budapest, Váci út 48/A-B

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EC CERTIFICATE(S): 93/42/EEC Annex V, Article 3 Quality Assurance System  
Production; Reg No.: OD 692410290001

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ACCESSORIES: Alternative and standard adult size cuffs, Bluetooth adapter, pouch for the device with belt, hardware key, 4pcs 1.5 V AA batteries, TensioMed TensioWin Software CD, User's Manual

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18.07.2011  
TensioMed Kft., Budapest, Hungary

  
Dr. Illyés Miklós  
Managing Director