DECLARATION OF CONFORMITY

MANUFACTURER:	TensioMed Kft. 1103 Budapest, Kőér u. 2/E Hungary
PRODUCT (name, group, type):	**TensioClinic**, arteriograph, TL2
CLASSIFICATION:	Class IIa, Rule 10 according to Annex IX of the MDD

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.

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
NOTIFIED BODY:	TÜV Rheinland IterCert Kft., 1008 H-1132 Budapest, Váci út 48/A-B
EC CERTIFICATE(S):	93/42/EEC Annex V, Article 3 Quality Assurance System Production; Reg No.: OD 692410290001
ACCESSORIES:	D-rings Cuff 01, 02, 03, Bluetooth adapter kit, protective pouch for device, hardware key, 4pcs 1.5 V AA batteries, measuring instrument to determine the distance from jugulum to symphysis, TensioMed Arteriograph software installation CD, User's Manual

18.07.2011
TensioMed Kft., Budapest, Hungary

Dr. Illyés Miklós
Managing Director