



DECLARATION OF CONFORMITY

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

PRODUCT (name, group, type): **TensioClinic**, arteriograph, TL1

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, IrDa adapter kit, pouch with an integrated console for holding the IrDa adapter, 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