

EC DECLARATION OF CONFORMITY

Manufacturer's name:	FREY Sp.J. 05-502 Piaseczno; ul. Wołodziejowskiego 38; Poland
Identification of device:	Chart panel
Model No.:	TCP-3000P
Classification:	Class I
Starting from this serial number:	NCAI001P

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC

Standards :

Harmonized Standards (published in the Official Journal of the European communities) applicable to this products are :

EN 60601-1:2006 (PN-EN 60601-1:2011)
EN 60601-1-2:2007 (PN-EN 60601-1-2:2007)
EN ISO 15004-1:2009 (PN-EN ISO 15004-1:2010)
EN 980:2008 (PN-EN 980:2010)
EN 1041:2008 (PN-EN 1041+A1:2013-12)

Date CE Mark was affixed: 01.03.2009

Piaseczno, 2016-10-17



Wojciech Frey
Managing Director

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