

## EC DECLARATION OF CONFORMITY

|                                   |                                                                                        |
|-----------------------------------|----------------------------------------------------------------------------------------|
| Manufacturer's name:              | <b>FREY Sp.J.</b><br><b>05-502 Piaseczno; ul. Wołodyjowskiego 38;</b><br><b>Poland</b> |
| Identification of device:         | Chart Panel                                                                            |
| Model No.:                        | TCP-2000P                                                                              |
| Classification:                   | Class I                                                                                |
| Starting from this serial number: | RGBD001D                                                                               |

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 :

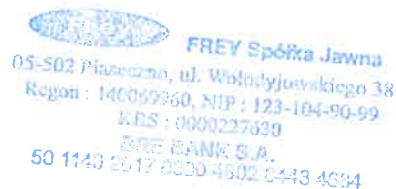
EN 60601-1:2006 (PN-EN 60601-1:2011)  
EN 60601-1-2:2007 (PN-EN 60601-1-2:2007)  
EN ISO 15004-1:2009 (PN-EN ISO 15004-1:2010)  
EN 980:2008 (PN-EN 980:2010)  
EN 1041:2008 (PN-EN 1041+A1:2013-12)

Date CE Mark was affixed: 01.07.2012

Piaseczno, 2016-10-17



Wojciech Frey  
Managing Director



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