

Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Polska,

Tel/fax +48 33 861 40 96

e-mail: office@infimed.pl

We hereby declare for our own responsibility, that

Medical device: Operating table

Name: VIVAX

Type: OT-02

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

covered by Technical file no 1.0, date 08.2013

Inspection documentation of device: Report of final inspection no 17.3.1.02

fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.

List of all harmonised standards required by Directive 93/42/EEC is indicated in Technical File.

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Prezes Zarządu
Piotr Koźbial
Piotr Koźbial

Place and date: Żywiec 02.12.2016

Name and surname:



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NIP 553-251-29-67
REGON 243274947
KRS 0000463933

Sąd Rejonowy w Bielsku-Białej, VIII Wydział
Gospodarczy Krajowego Rejestru Sądowego.
Wysokość Kapitału Zakładowego: 500 000 PLN

bank Bank Spółdzielczy
w Węgierskiej Górze
SWIFT POLUPLPR

78 8131 0005 0016 2492 2000 0010 **PLN**
PL02 8131 0005 0016 2492 2000 0020 **EUR**
PL23 8131 0005 0016 2492 2000 0030 **USD**

List of all harmonised standards required by Directive 93/42/EEC:

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN ISO 19054:2006	Rail systems for supporting medical equipment (ISO 19054:2005)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)



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EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-46:1998	Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



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