INFIMED

# 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

CE

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INFIMED Sp. z o. o.
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tel./fax 33 861 40 96
NIP: 5532512967 REGON: 243274947
(4)

Prezes Zarządu
Piotr Koźbiał

Place and date: Żywiec 02.12.2016

Name and surname:



Digitally signed by Grabazei Alexandru
Date: 2021.11.03 09:31:57 EET
Reason: MoldSign Signature
Location: Moldova

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

bank Bank Spółdzielczy w Węgierskiej Górce
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

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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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