

## 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](mailto:office@infimed.pl)

### We hereby declare for our own responsibility, that

Medical Device: Treatment light

Name: ONYX

Type: TL-01

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 17.3.1.12

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

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Prezes Zarządu  
*Piotr Kozbial*  
Piotr Kozbial

Place and date: Żywiec 02.12.2016

Name and surname:



adres INFIMED Sp. z o.o.  
ul. Kabaty 1,  
34-300 Żywiec, Polska

tel/fax +48 33 861 40 96  
email [office@infimed.pl](mailto:office@infimed.pl)  
www [www.infimed.pl](http://www.infimed.pl)

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 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)
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 60601-2-41:2009 + A11:2011	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
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



INFIMED Sp. z o.o.  
adres ul. Kabaty 1,  
34-300 Żywiec, Polska

tel/fax +48 33 861 40 96  
email office@infimed.pl  
www www.infimed.pl

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 Górcze  
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