INSTITUTE FOR TESTING AND CERTIFICATION
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ZLÍN, T. Bati 299, CZECH REPUBLIC

FINAL REPORT

Ref. No. 803600371/2008

Applicant: **MEDICAM, Inc.**

Address: **5285 Queen Mary Road, Montreal, Quebec Canada, H3W 1Y3**

Product: **IPL Hair Removal & Photo Rejuvenation System**

Models: **MD-IPL7**
MD-IPL9

Assessed by: **Peter Korbel**

Issued on: **5th August 2008**

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Introduction

This final report is based on the manufacturer's request lodged in the application No. 803600371 registered 10th April 2008 for conformity assessment of Class IIa medical devices pursuant to the essential requirements of the Council Directive 93/42/EEC.

The aim of this assessment is to make evident the fulfillment of the safety requirements specified by the European law and to facilitate the placing of the certified products to the EU market.

1. Product specification

The certified products: IPL Hair Removal & Photo Rejuvenation System, models: MD-IPL7 and MD-IPL-9, is the pulse light therapeutic device designed to treat various skin and hair abnormalities such as freckles, chloasma, acne, etc. and smooth small wrinkles, shrink pores, beautify and whiten the skin, including face neck, chest and hands.

The applicant is the own brand labeling manufacturer of the certified product and he has following identification data:

Company name:	MEDICAM, Inc.
Address:	5285 Queen Mary Road, Montreal, Quebec, Canada, H3W 1Y3
Company Id. No.:	1162664354

A detailed description of the product design including drawings and a material specification is included in the Technical File, No.: PL-001, issued by the OEM manufacturer.

1.1. Intended use of the products

The IPL Hair Removal & Photo Rejuvenation System, models: MD-IPL7 and MD-IPL-9, is the pulse light therapeutic device intended to use for the treatment of various skin and hair abnormalities such as freckles, chloasma, acne, etc. and smooth small wrinkles, shrink pores, beautify and whiten the skin, including face neck, chest and hands.

1.2. Medical devices classification

The certified products have been classified by the manufacturer according to the Annex IX of the Medical Device Directive 93/42/EEC as Class IIa medical devices. They are active therapeutic devices for which the Rule 9 shall apply.

1.3. Manufacturing site

The certified products are placed on the market by the company: MEDICAM, Inc., 5285 Queen Mary Road, Montreal, Quebec, H3W 1Y3 Canada. These medical devices are manufactured by the original equipment manufacturer (OEM): Weifang Huamei Electronics Co., Ltd., No: 338, Dongfengdongjie Street, Kuiwen District, Weifang, China, on the OEM-OBL contractual basis.

2. Product properties conformity with requirements given by regulations

2.1. Applicable regulations

Safety and functionality of the device shall conform to the essential requirements laid down by the Council Directive 93/42/EEC (Medical Devices Directive MDD), as amended.

The requirements of the mentioned Directive are approximated into Czech national legislation by the means of the Government Order No. 336/2004 Coll. Conformity to this Government Order means also the conformity to the appropriate Directive and vice versa.

In case of existing harmonized European standards, the compliance to the harmonized EN standard gives a presumption of conformity.

2.2. Technical standards and specifications

A list of the harmonized standards and other technical specification specifying the essential requirements of the above mentioned directive related to the certified products is presented in the table No. 1.

Table No. 1: Standards and specifications applied for the conformity assessment process

	Standard No.	Standard Name
1	EN ISO 14971:2003	Medical devices - Application of risk management to medical devices
2	EN ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN 60601-1:2001	Medical electrical equipment - Part 1: General requirements for safety
4	EN 60601-1-2:2002	Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	EN 60825-1:2001	Safety of laser products - Part 1: Equipment classification, requirements and user's guide
6	EN 60601-1-4:1999	Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems
7	EN 1041:1998	Information supplied by the manufacturer with medical devices
8	EN 980:2003	Graphical symbols for use in the labeling of medical devices
9	MDD 93/42/EEC	Council Directive on Medical Devices

2.3. Chosen conformity assessment procedure

The Class IIa medical devices delivered are subject of conformity assessment procedures described in Article 11 of the 93/42/EEC directive (MDD). The OEM manufacturer has decided to apply the procedure described in the Article 11 (3), letter a, based on the procedure described in Annex II (Full quality assurance), excluding the point 4 of the Annex II.

3. Assessment of the manufacturer's quality system

The OBL manufacturer Medicam, Inc. has established internal quality system. The OEM manufacturer Weifang Huamei Electronics Co., Ltd., No: 338, Dongfengdongjie Street, Kuiwen District, Weifang, China has established Full Quality Assurance System according to Annex II of MDD 93/42/EEC which was certified by ITC, Inc., Notified Body No.1023, Zlín, Czech Republic and issued EC certificate no.: 07 0779 QS/NB is valid until 27th December 2012.

4. Manufacturer's quality system surveillance

For confirmation that both OEM and OBL manufacturers duly fulfils the obligation imposed by the approved quality system the periodic surveillance audits and assessments shall be conducted by the Notified Body No. 1023 at least once a year. Positive results of the system review provide for the continuing placing of the assessed medical devices on the EU market.

The manufacturer shall inform the Notified Body No. 1023 of any plan of substantial changes of the quality system and/or the products covered by present conformity assessment and submit the documentation necessary for assessment of the changes and verification of the permanent system compliance to the directive 93/42/EEC.

5. The conclusions and decision of the Notified Body No. 1023

Based on the documentation review, on the valid EC certificate of the OEM manufacturer's quality system relating to the assessed products, and the OBL manufacturer's quality system, the Notified Body No. 1023 concludes that the OBL manufacturer applies internal quality system ensuring that the assessed products conform to the provisions of the Council Directive No. 93/42/EEC (MDD) which apply to them at every stage of process, from design to final inspection.

The Notified Body No. 1023 has approved the OEM manufacturer's quality system and OBL manufacturer's quality assurance system related to the assessed product range.

The Notified Body No. 1023 decided to issue EC Certificate confirming fulfilling of the MDD Directive essential requirements.

After fulfilling of all obligation specified in clauses 1 to 2 of Annex II to MDD directive 93/42/EEC, as amended, the manufacturer shall issue EC Declaration of Conformity. Fulfilling these obligation, the manufacturer is authorized to affix the CE marking followed by the number of the Notified Body (1023) on each product (and/or on its packaging) of the specified type.

Before placing the first product of the certified type on the EU and/or EFTA market, the manufacturer shall establish and register an authorized representative having his place of business in one EU/EFTA member state.

The graphical shape of the CE mark is presented in the Council Decision No. 93/465/EEC of 22nd July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE marking, which are intended to be used in the technical harmonization directives.

6. List of documents applied in the conformity assessment process

a) Application for certification No. 803600371 registered 10th April 2008

b) Agreement No. 1042006 between OEM and OBL manufacturers signed 10th April 2008

c) Council Directive 93/42/EEC of 14th June 1993 concerning medical devices as amended

d) Medicam Inc.: MD-IPL7 (MD-IPL9) User Manual

e) Medicam Inc.: Draft of labels for model MD-IPL7 and MD-IPL9

f) Weifang Huamei Electronics, Co., Ltd.: Technical Construction File covered IPL models (Doc. No. PL-001-1--12), dated 10/08/2007

The technical document contains product description, product specifications, description of the intended use and operation, draft of labeling and instruction for use, description of manufacturing

process, essential requirements, list of specified standards, risk analysis, clinical data and results of clinical evaluation, post marketing and surveillance system, EC declaration of conformity, etc.

g) Final Report no. 803600290A/2007 issued by Institute for testing and certification Inc., NB 1023, covered IPL models manufactured by OEM manufacturer Weifang Huamei Electronics, Co., Ltd.

h) EC certificate no. 07 0779 QS/NB issued by Institute for testing and certification Inc., NB 1023, covered all IPL models manufactured by OEM manufacturer Weifang Huamei Electronics, Co., Ltd., valid until 27th December 2012.