FINAL REPORT
Ref. No. 803600225/2007

Applicant: POLYX TRADE International, Ltd.
Address: Sreznevskeho 17, 831 03 Bratislava
SLOVAKIA

Manufacturer: PKF “SIM-Technika” Ltd.
Address: Chkalova str. 2, 150054 Yaroslavl, RUSSIA

Product: Electroimpedance Computer
Mammograph “MEIK”

Assessed by: Ing. Peter Korbel

Issued on: 20th November 2007

RNDr. Radomir Čevelík
Representative of the Notified Body No. 1023
Introduction

This final report is based on the manufacturer’s request lodged in the application No. 803600225 registered 18th June 2007 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 medical device is Electroimpedance Computer Mammograph “MEIK” for screening examination of mammary glands via visualization of electroconductivity distribution. The medical device has been placed on the Russian market and the Ukraine market in the year 2003.

The applicant is EC representative of the manufacturer and has following identification data:
Company name: POLYX TRADE International, Ltd.
Address: Sreznovskoho 17, 831 03 Bratislava, SLOVAKIA
Company Id. No.: 35874945

The manufacturer of the certified product has following identification data:
Company name: PKF “Sim-Technika” Ltd.
Address: Chkalova str. 2, 150054 Yaroslavl, RUSSIA

A detailed description of the product including check list of essential requirements according to MDD 93/42/EEC, risk analysis acc. EN ISO 14971, test reports according CSN EN 60601-1 and CSN EN 60601-1-2, material specification, clinical studies, user manual, registration and licence documents issued by regulatory bodies in Russia.

1.1. Intended use of the products

The certified product: Electroimpedance Computer Mammograph "MEIK" is intended for early diagnosis of malignant tumors without utilizing of ionizing radiation and other potentially dangerous procedures. Scope of utilization is mammology, oncology, obstetrics, gynecology, etc. Diagnostic possibilities: seven tomographic scanning planes, scanning depth from 0.4cm to 4.6 cm, software for measurements control, processing and storage of data, color image processing, filtering and automatic analysis.

1.2. Medical devices classification

The certified product has been classified by the manufacturer according to the Annex IX of the Medical Device Directive 93/42/EEC as a Class IIa medical device. It is a non-invasive device for which the Rule 3 shall apply.

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

<table>
<thead>
<tr>
<th>Id</th>
<th>Document No.</th>
<th>Document Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EN ISO 14971:2003</td>
<td>Application of risk management to medical devices</td>
</tr>
<tr>
<td>2</td>
<td>EN 60601-1:1997</td>
<td>Medical electrical equipment. General requirements for safety</td>
</tr>
<tr>
<td>3</td>
<td>EN 60601-1-2:2001</td>
<td>Medical electrical equipment. General requirements for safety. Electromagnetic compatibility. Requirements and tests</td>
</tr>
<tr>
<td>4</td>
<td>EN 1041:1998</td>
<td>Information supplied by the manufacturer with medical devices</td>
</tr>
<tr>
<td>5</td>
<td>EN 980:2003</td>
<td>Graphical symbols for use in the labeling of medical devices</td>
</tr>
<tr>
<td>6</td>
<td>MDD 93/42/EEC</td>
<td>Council directive concerning medical devices</td>
</tr>
<tr>
<td>7</td>
<td>EN ISO 13485:2003</td>
<td>Medical devices - Quality management systems. Requirements for regulatory purposes</td>
</tr>
</tbody>
</table>

2.3. Chosen conformity assessment procedure

The Class IIa medical devices delivered in non-sterile conditions are subject of conformity assessment procedures described in Article 11 of the 93/42/EEC directive (MDD). The 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 manufacturer’s quality system assessment has been carried out by the examination of the quality system documentation, as performed by Mr. Peter Korbel, (the ITC expert), and by the inspection of manufacturer’s premise performed by ITC auditors staff, namely Mr. Zvyagin I. M. (lead auditor), Ms. Shefova L. M. (auditor). The inspection audit in the company PCF “Modern Impedance Medical Engineering” Ltd. (PCF “SIM-technics” Ltd.) has been performed on 20th September 2007.

The manufacturer’s quality system relating to the above mentioned product range has been created and satisfactorily documented according to harmonized standard EN ISO 13485:2003.

The course of the audit and its results are described in the NB 1023 Audit Report No. 803600225.

4. Manufacturer’s quality system surveillance

For confirmation that the manufacturer duly fulfills 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 and on the audit of the manufacturer's quality system relating to the assessed products, the Notified Body No. 1023 concludes that the manufacturer applies a 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 quality system complies also with requirements of the standard EN ISO 13485:2003 harmonized to the directive 93/42/EEC which requirements are implemented in the Czech Government Order No. 336/2004 Collection of Laws.

The Notified Body No. 1023 has approved the 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. 803600225 registered 18th June, 2007
c) PKF "SIM-Technika" Ltd.: Technical File of Electroimpedance Computer Mammograph “MEIK”
d) PKF "SIM-Technika" Ltd.: Essential Requirement Checklist, Doc. No.: TF-ER-01, 13.09.2007
e) PKF "SIM-Technika" Ltd.: Risk Analysis according to EN ISO 14971, Doc. No.: TF RA14971 14.09.2007
f) Institute for Testing and Certification, Inc., Testing Laboratory No.1004.3: Electric Safety Test according to STN EN 60601-1, Report, Ref. no.:3328/07, issued 4.9.2007
g) Institute for Testing and Certification, Inc., Testing Laboratory No.1004.3: EMC Test Report according to STN EN 60601-1-2, Ref. no.:3664/07, issued 12.9.2007
h) PKF "SIM-Technika" Ltd.: Summary of Clinical Studies
i) Ministry of Health of the Russian Federation: Registration certificate No.: 29/05010303/5320-03
j) Federal Service for Supervision in the Field of Consumers Rights Protection and Human Well-Being: SANITARY AND EPIDEMIOLOGICAL CERTIFICATE No.:77.99.34.944.D.007393.08.06

k) System for Certification GOST R: CERTIFICATE OF CONFORMATION, No.: ROSS.RU IM02.V14247

l) Russian Register Certification System: CERTIFICATE OF QUALITY MANAGEMENT SYSTEM CONFORMITY in accordance with the requirements of ISO 13485:2003, No.:05.337.026

m) IQNet and Certification Association Russian Register: CERTIFICATE OF MANAGEMENT SYSTEM in accordance with ISO 9001:2000.

n) PKF “SIM-Technika” Ltd.: Authorization of EC representative

o) PKF “SIM-Technika” Ltd.: User’s Manual