begl. Fotokopie

analyticon
Biotechnologies AG

DECLARATION OF CONFORMITY /

Name and address of the firm	analyticon Biotechnologies AG Am Mühlenberg 10 D-35104 Lichtenfels Germany

We declare under our sole responsibility that

the in vitro diagnostic medical device	**LabStrip U11 plus** (siehe Anlage) (Urine Multi-Constituent Test Strips) Name, type or model, batch or serial number, possibly sources and number of items

classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

- ☐ Device of List A, Annex II
- ☐ Device of List B, Annex II
- ☐ Device for self-testing not listed in Annex II
- ☒ Other device

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Applied common technical specifications, harmonised standards, national standards or other normative documents	
Conformity assessment procedure	Nach „Richtlinie über In-vitro-Diagnostika 98/79 EG“, Anhang III, Art. 1-5 in Eigenbewertung, EDMS-Nomenklatur Code: 11.70.02.02 (Urine Multi-Constituent Test Strips) Regierungspräsidium Kassel, Behörde DE/CA30 Registriernummer: DE/CA30 / HE – 0033 – 10001 - 000
Notified Body (if consulted)	

Lichtenfels, 08.06.2005

Dr. Bernhard Meisegeier
Sicherheitsbeauftragter

ELECTRONIC TECHNOLOGY SYSTEMS
DR. GENZ GMBH

COMPETENT BODY / ACCREDITED TEST HOUSE

EC DECLARATION OF CONFORMITY

This certifies that the following designated product

URINANALYSER
MODEL NO. : LABUREADER PLUS

(Product identification)

complies with the essential protection requirements of Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility.
This declaration applies to all specimens manufactured in accordance with the attached manufacturing drawings which form part of this declaration.
Assessment of compliance of the product with the requirements relating to electromagnetic compatibility was based on the following standards:

EN 61326 : 1997, EN 55022, EN 61000-3-2 /-3
EN 61000-4-2 /-3 /-4 /-5 /-6 /-11

(Identification of regulations / standards)

This declaration is the responsibility of the manufacturer / importer

77 ELEKTRONIKA
FEHERVARI UT 98 ,
H-1116 BUDAPEST, HUNGARY

(Name / Address)

CE ETS Germany EMC tested

THIS DOC IS ONLY VALID IN CONNECTION WITH THE TEST REPORT NUMBER : G0M20210-7189-E-16

MANUFACTURER / IMPORTER

TEST LABORATORY

This is the result of test, that was carried out from the submitted type-samples of a product in conformity with the specification of the respective standards.
The certificate holder has the right to fix the CE-mark for EMC on the product complying with the inspection sample.

(Date)

(Surname, forename)
(Company stamp)

ELECTRONIC TECHNOLOGY SYSTEMS • DR. GENZ GMBH •

December 23, 2002
(Date)

Dr. Genz
(Company stamp)

ELECTRONIC TECHNOLOGY SYSTEMS DR. GENZ GMBH
STORKOWER STRASSE 38C, D-15526 REICHENWALDE B. BERLIN, GERMANY, PHONE + 49-33631-888 00 FAX + 49-33631-888 660

ELECTRONIC TECHNOLOGY SYSTEMS
DR. GENZ GMBH

COMPETENT BODY / ACCREDITED TEST HOUSE

EC DECLARATION OF CONFORMITY

This certifies that the following designated product

IVD, URINE STRIPREADER, REFLECTION PHOTOMETER
MODEL NO. : LABUREADER UAP-9901-1

.....
(Product identification)

complies with the essential protection requirements of Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility.
This declaration applies to all specimens manufactured in accordance with the attached manufacturing drawings which form part of this declaration.
Assessment of compliance of the product with the requirements relating to electromagnetic compatibility was based on the following standards:

EN 50081-1 /1992: EN 55022, EN 61000-3-2/-3
EN 50082-1 /1997: EN 61000-4-2/-3/-4/-5/-6/-8/-11, ENV 50204

.....
(Identification of regulations / standards)

This declaration is the responsibility of the manufacturer / importer

77ELEKTRONIKA KFT
FEHERVARI STR. 98,
H-1116 BUDAPEST,

.....
(Name / Address)

CE ETS Germany EMC tested

THIS DOC IS ONLY VALID IN CONNECTION WITH TEST REPORT NUMBER : 12039903

MANUFACTURER / IMPORTER

.....
(Date)

.....
(Surname, forename)
(Company stamp)

TEST LABORATORY

This is the result of test, that was carried out from the submitted type-samples of a product in conformity with the specification of the respective standards.
The certificate holder has the right to fix the CE-mark for EMC on the product complyi-ng with the inspection sample.

March 12, 1999
.....
(Date)

Dr. Genz

.....
Dr. Genz

ELECTRONIC TECHNOLOGY SYSTEMS DR. GENZ GMBH
STORKOWER STRASSE 38C, D-15526 REICHENWALDE B. BERLIN, GERMANY, PHONE + 49-33631-88800 FAX + 49-33631-88866

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer

manufacturer: 77 Elektronika Műszeripari Kft.
address: 1116 Budapest, Fehérvári út 98.

herewith declares that product product identification:

"DocUReader" analyzer for 11 parameter urine reagent strips

is in conformity with the provisions of the following EC directive(s)
(including all applicable amendments)

reference No.	Title
98/79/EC	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices Annex IV

References of standards and/or technical specifications applied for this declaration of conformity, or parts thereof:

harmonized standards:

No.		Title:	Parts:
EN 24180-1	1993	Guide to compilation of performance test schedules for complete, filled transport packages. General principles	
EN 24180-2	1993	Guide to compilation of performance test schedules for complete, filled transport packages. Quantitative data	
EN 50082-1	1994	Electromagnetic compatibility. Generic immunity standard. Residential, commercial and light industry	
EN 50081-1	1993	Electromagnetic compatibility. Generic emission standard. Residential, commercial and light industry	
EN 55011	1991	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	
EN 60601-1-2	1993	Medical electric devices and equipment	
EN 14971		Medical devices risk management	
EN 1658	1997	Requirements for marking of in vitro diagnostic instruments	
EN 980	1997	Graphical symbols for use in the labelling of medical devices	
EN 61010-1:1990 A1:1992 A2: 1995		Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment	

77 Elektronika Műszeripari Kft.
H-1116 Budapest, Fehérvári út 98.
23.

Budapest, 2003-01-29 András Kövesi 77 Elektronika Quality Assurance Director

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer
manufacturer: 77 Elektronika Műszeripari Kft.
address: 1116 Budapest, Fehérvári út 98.

or representing the manufacturer's authorized representative established within the Community (or the EEA) indicated hereafter (when applicable)

authorized representative:
B.o.c.z.k.o. Handelsvertretung und Kooperationsberatung
address: D-67346 Speyer, Gilgenstr. 15/b Deutchland

herewith declares that product product identification: **OPTILITE blood glucose meter** for personal use

is in conformity with the provisions of the following EC`directive(s)

(including all applicable amendments)

reference No.	Title
98/79/EC	DIRECTIVE 98/79/EC OF THE EU PARLIAMENT AND OF THE COUNCIL on *in vitro* diagnostic medical devices Annex IV.

and that the standards and/or technical specifications referenced have been applied.
Notified Body certificate No: SY 211141201 was issued by TRPS 2001/11/21

References of standards and/or technical specifications applied for this declaration of conformity, or parts thereof:

harmonized standards:

No.	Issue:	Title:	Parts(1):
EN 1441	1997	Medical Devices - Risk analysis	
EN 13532	2002	General requirements for in vitro diagnostic medical devices for self-testing	
EN 15197	2000	Determination of performance criteria for IVD Blood Glucose systems	
EN 61010-1	2001	Safety requirements for elecrtical equipment for measurement, control and laboratory use Part 1: General requirements	
EN 1658	1996	Requirements for marking of in vitro diagnostic instruments	
EN 980	1999	Graphical symbols for use in the labelling of medical devices	
EN 592	2002	Instructions for use for in vitro diagnostic instruments for self-testing	
EN 60601-1-2	2001	Medical electrical equipment -- Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests	

Last two digits of the year in which the CE marking was affixed:02

77 Elektronika Műszeripari Kft.
H-1116 Budapest, Fehérvári út 98.
23.

Budapest, 2003-02-04 András Kövesi 77 Elektronika Quality Assurance Director

(1) Where appropriate the applicable parts or clauses of the standard or the technical specification shall be referenced.

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer

manufacturer: 77 Elektronika Műszeripari Kft.
address: 1116 Budapest, Fehérvári út 98.

or representing the manufacturer's authorized representative established within the Community (or the EEA) indicated hereafter (when applicable)

authorized representative: B.o.c.z.k.o. Handelsvertretung und Kooperationsberatung
address: D-67346 Speyer, Gilgenstr. 15/b Deutchland

herewith declares that product product identification: **Optilite Test Strip (OPL-9901-1)**

is in conformity with the provisions of the following EC directive(s)

(including all applicable amendments)

reference No.	title
98/79/EC	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on *in vitro* diagnostic medical devices Annex IV.

and that the standards and/or technical specifications referenced overleaf have been applied.
Notified Body certificate No: HL02111411-0001 was issued by TRPS 2002.04.22

References of standards and/or technical specifications applied for this declaration of conformity, or parts thereof:

harmonized standards:

No.	Issue:	Title:	Parts(1):
EN 1441	1997	Medical devices- Risk analysis	
EN 15197	2000	Determination of performance criteria for IVD Blood Glucose systems	
EN 13640	2002	Stability testing of in vitro diagnostic medical devices	
EN 980	1997	Graphical symbols for use in the labelling of medical devices	
EN 376	2002	Information supplied by the manufacturer with in vitro diagnostic reagents for self testing	

Last two digits of the year in which the CE marking was affixed: 02

77 Elektronika Műszeripari Kft.
H-1116 Budapest, Fehérvári út 98.
23.

Budapest, 2003-06-19 András Kövesi 77 Elektronika Quality Assurance Director

(1) Where appropriate the applicable parts or clauses of the standard or the technical specification shall be referenced.