





Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



Product Service

## EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

No. V1 052126 0042 Rev. 01

### Model(s):

1. Blood Glucose Measuring Systems For Self-Testing:  
Blood Glucose Monitoring System  
TD-41XX, TD-42XX (X=0-9, A-Z or blank), MEDISAFE EX  
Blood Glucose Meter  
TD-41XX, TD-42XX (X=0-9, A-Z or blank),  
Blood Glucose Plus Blood Pressure Monitoring System  
TD-32XX (X=0-9, A-Z or blank), MD-300,  
Blood Glucose Plus Blood Pressure Meter  
TD-32XX (X=0-9, A-Z or blank), MD-300,  
Blood Glucose Test Strip  
TD-43XX (X=0-9, A-Z or blank),  
Blood Glucose Control Solution  
TD-49XX (X=0-9, A-Z or blank),
2. Pregnancy Test Systems:  
Digital Pregnancy Test  
TD-52XY (X=0-4, Y=0-9, A-Z or blank),  
Pregnancy Test and Test Strip  
TD-53XY (X=0-4, Y=0-9, A-Z or blank),  
TD-45XY (X=0-4, Y=0-9, A-Z or blank),
3. Ovulation Test Systems:  
Digital Ovulation Test  
TD-52XY (X=5-9, Y=0-9, A-Z or blank),  
Ovulation Test and Test Strip  
TD-45XY (X=5-9, Y=0-9, A-Z or blank),  
TD-53XY (X=5-9, Y=0-9, A-Z or blank),
4.  $\beta$ -Ketone Test Strip:  
TD-463X (X=0-9, A-Z or blank),
5. Blood Glucose Plus  $\beta$ -Ketone Monitoring System:  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)  
Blood Glucose Plus  $\beta$ -Ketone Meter:  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
6.  $\beta$ -Ketone Monitoring System  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)  
 $\beta$ -Ketone Meter  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
7. Blood glucose Plus  $\beta$ -Ketone control solution:  
TD-49XX (X=0-9, A-Z or blank)
8. Blood glucose, total cholesterol and uric acid  
multi-Monitoring system:  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)  
Blood glucose, total cholesterol and uric acid  
multi Meter  
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
9. Total Cholesterol Test Strip:  
TD-464X (X=0-9, A-Z or blank)
10. Uric Acid Test Strip:  
TD-465X (X=0-9, A-Z or blank)
11. Total Cholesterol control solution  
TD-49XX (X=0-9, A-Z or blank)
12. Uric acid control solution

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No. V1 052126 0042 Rev. 01

TD-49XX (X=0-9, A-Z or blank)

For the product category (ies):

Blood glucose measuring systems for self testing,  
Pregnancy and Ovulation test system,  $\beta$ -Ketone  
Test Strip, Blood Glucose Plus  $\beta$ -Ketone Meter,  
Blood Glucose Plus  $\beta$ -Ketone Monitoring System,  
 $\beta$ -Ketone Meter,  $\beta$ -Ketone Monitoring System, Blood  
glucose Plus  $\beta$ -Ketone Control solution, Blood glucose,  
total cholesterol and uric acid multi-Meter, Blood glucose,  
total cholesterol and uric acid multi-Monitoring system,  
Total Cholesterol control solution, Uric acid control  
solution, Total Cholesterol Test Strip, Uric Acid Test Strip.

Facility(ies):

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