

EC Declaration of conformity for In-vitro-diagnostics

according to annex III of directive 98/79/EC for In-vitro-diagnostics

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+A1:2007.



We

Name of manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following test sticks for professional use

Name of product	Reference numbers
Medi-Test Combi 10 [®] SGL	930 67, 930 77
Medi-Test Combi 11	930 60, 930 871
Medi-Test Combi 10 [®] L	930 79, 930 58
Medi-Test URYXXON [®] Stick 10	930 68, 930 872
Medi-Test Combi 10 [®]	930 56
Medi-Test Combi 9 [®]	930 11, 930 23, 930 80
Medi-Test Combi 8 L	930 21
Medi-Test Combi 7	930 10, 93022
Medi-Test Combi 6 A	930 13, 930 34
Medi-Test Combi 6	930 18, 930 78
Medi-Test Combi 5 S	930 55
Medi-Test Combi 5 N [®]	930 35, 930 36
Medi-Test Combi 5	930 09, 930 32
Medi-Test Combi 3 A [®]	930 07, 930 30
Medi-Test Urbi	930 12, 930 33

Type: URINE MULTI-CONSTITUENT TEST STRIPS
EDMS 11-70-02-02-00

Registration number: DE/CA21/DE/CA21/MACHEREY/2002/06/IVD/0001

and the following reflectometers for professional use

Name of product	Reference numbers
URYXXON [®] 300	930 69
URYXXON [®] 500	930 080
URYXXON [®] Relax	930 88

Type: URINE MULTI-CONSTITUENT TEST STRIPS
EDMS 11-70-02-02-00

Registration number: DE/CA21/DE/CA21/MACHEREY/2003/11/IVD/0005

and the following control solutions

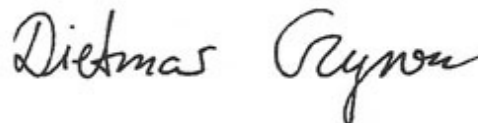
Name of product	Reference number
Medi-Test Control	930 38
Type:	Other calibrators and standards (CC) EDMS 11-50-03-90-00
Registration number:	DE/CA21/Macherey/2002/11/IVD/0007

and the following sticks for patient self-testing

Name of product	Reference numbers
Medi-Test Glucose	930 01, 930 24
Medi-Test Glucose 3	930 03, 930 26
Medi-Test Protein 2	930 04, 930 27
Medi-Test Keton	930 05, 930 28
Medi-Test Nitrit	930 06, 930 29
Medi-Test Combi 2	930 15, 930 37
Type:	Urine test strips, for self-testing EDMS 11-70-02-90-00, OTHER URINE TESTING
Registration number:	DE/CA21/MACHEREY/2002/11/IVD/0002/Ä

are manufactured in compliance with the European Directive 98/79/EC.

Dueren, 14. April 2010



i.A. D. Czyron (QA Manager)