

## EC Declaration of Conformity

# EC Declaration of Conformity for *In-vitro* Diagnostic Products

The conformity is declared according to European IVD Regulation 2017/746 Annex IX, based on a full quality management system according to EN ISO 13485:2016 + AC:2016 and an assessment of the Technical Documentation.

<b>Name of manufacturer</b>	MACHEREY-NAGEL GmbH & Co. KG
<b>Address:</b>	Valencienner Str. 11 D - 52355 Düren Germany
<b>Single Registration number (SRN)</b>	DE-MF-000005636

<b>Name of product</b>	<b>Reference numbers</b>
Medi-Test Glucose	93001.005 93001.203880

**Intended purpose:** Medi-Test Glucose urine test strips are test strips which are suitable for measuring the glucose content of human urine. The test strips yield semiquantitative results in the range of 0–1000 mg/dL. The test strips can be read by comparing them visually with the colour scale. The results are used as a diagnostic aid for screening for diabetes mellitus and renal glycosuria, for example, during pregnancy. The urine test strips are suitable for self-testing.

**Risk class:** Class B

**Notified body 0197:** TÜV Rheinland LGA Products GmbH  
Tillystr. 2. 90431 Nürnberg

**Technical documentation assessment certificate:** IX 1038121-3

**Quality management system certificate:** HX 1038121-1

**Basic UDI-DI:** 4046681151057WA

**Applicable Common Specifications:** n.a.

We confirm that the product listed above is manufactured and QC controlled in compliance with the European IVD Regulation 2017/746. The manufacturer is exclusively responsible for the declaration of conformity.

Düren, 28.09.2023



ppa. Dr. Markus Meusel (QAM, Manager Reg. Affairs)

