

**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

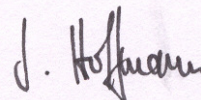
**Name of producer:** MACHEREY-NAGEL GmbH & Co. KG  
**Address:** MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Strasse 6-8  
52355 Dueren  
Germany

confirm that the following test strips

**Reference number:** 921 35  
**Name of product:** pH-Fix 3.1-8.3 test strips  
**Type:** Test strips for the determination of the pH-value in saliva  
EDMS 11-70-90-90-00  
**Registration number:** DE/CA21/ /MACHEREY/2002/11/IVD/0009

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

Dueren, April 01 2011



i.A. Dr. Hoffmann (QC)