

**EC Declaration of conformity for medical devices
 (according to annex II directive 93/42/EC for medical devices and to annex III
 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

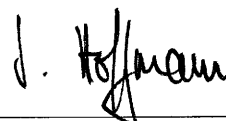
Name of producer: MACHEREY-NAGEL GmbH & Co. KG
Address: MACHEREY-NAGEL GmbH & Co. KG
 Neumann-Neander-Str. 6-8
 D- 52355 Dueren
 Germany

confirm that the following test sticks

Reference number: 92130
Name of product: pH-Fix 3,6-6,1 test strips
Type: Class I
 Test strips for the control of acid residues in dialyzers
Registration number: DE/CA21/MACHEREY/2004/06/A/0001
Type: Test strips for the determination of the vaginal pH-value
 EDMS 11-70-90-90-00
Registration number: DE/CA21/ /MACHEREY/2002/11/IVD/0006

are manufactured in compliance with the European Directive 93/42/EC and 98/79/EC.

Dueren, December 01, 2009



i.A. Dr. Hoffmann (QC)