

Declaration of Conformity

LEGAL MANUFACTURER: Siemens Healthcare Diagnostics Inc.
Tarrytown, NY 10591-5097
USA

PLACE OF MANUFACTURE: Kimball Electronics Poland Sp z 0.0
ul. Poznanska 1/C
tarnowo podgorne Poland 62080

PRODUCT: Visual & Instrument Read strips

PRODUCT CATEGORY: See Attachment 1

CLASSIFICATION: Self Declaration

CONFORMITY ASSESSMENT ROUTE: Annex III Applied

STANDARDS APPLIED: ENISO13485:2003 – Quality System for Medical Devices

DOCUMENT SYSTEM MANAGEMENT No: 44-35-02-D
REV: 1.0

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA



Noor Malki April 13/2011
Director – Regulatory Affairs - POC Date

