European Communities Council Directive 98/79/EC
Concerning *In Vitro Diagnostic* Medical Devices

EC DECLARATION OF CONFORMITY
STL-DCP-INS-001

Validity declaration of conformity from date / Date de déclaration de conformité

Place / Lieu d' émission: **bioMérieux, Inc. Durham, North Carolina**
Declaration of Conformity Date / Date de validité de la declaration de conformité:
12 February 2009

Description of the product / Description du produit
Name / Nom: **DensiCHEK™ Plus Instrument and Accessories**
Type, Model, or Product Number / Type, modèle, ou Référence Produit:
VITEK 2 Compact (120/220V) Instrumentation can be configured from:
21250 DensiCHEK Plus
21255 DensiCHEK Plus Standards Kit
21254 DensiCHEK Spare Parts Kit

Identification of the person who has the power of attorney to bind the manufacturer to this declaration / idendification du signataire représentant le fabricant

Name / Nom: **Sandra Perreand**

Title / Titre: **Senior Director, North America Regulatory Affairs**

Signature / Signature: Sandra Perreand Feb 12, 2009

Identification of the legal entity / Identification de l'entité légale

Manufacturer / Fabricant

Name / Nom: **bioMérieux, Inc.**

Address / Adresse: **100 Rodolphe Street, Durham, N.C. 27712, United States**

S.Đ.N: 0106034369 - C.T.T.N.H.H
CÔNG TY TNHH
BIOMÉRIEUX
VIỆT NAM
QUẬN ĐỐNG ĐA-T.P HÀ NỘI

Statement of Conformity / Déclaration de Conformité

We, the manufacturer hereby declare that the above mentioned products comply with the Directive(s) and its relevant transposition into all national laws of the member states into which we place the product(s).

Nous, fabricant, déclarons que les produits mentionnés ci-dessus satisfont avec les Directives et leur transposition en droit national dans les Etats Membres dans lesquels les produits sont places

Authorized Representative / Représentant autorisé

Name / Nom: **bioMérieux SA**

Address / Adresse: **Chemin de l'Orme, 69280 Marcy l'Etoile, FRANCE**

Conformity Assessment Procedure Demonstrating compliance / Procédure d'évaluation de conformité choisie

Annex **III (section 6 excluded) / Annexe III (section 6 exclue)**

Directive(s): **European Communities Council Directive 98/79/EC Concerning *In Vitro Diagnostic* Medical Devices**

List of Relevant Standards / Documents normatifs appliqués

ISO 13485:2003 Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001

ISO 9001:2000 Full Quality System

IEC/EN 61010-1:2001

IEC/EN 61010-2-010:2002

EN 60825-1:2002

EN 61326-1:1997 + A1:1998 + A2:2001 + A3:2003 (Class B)

CAN/CSA-C22.2 No. 61010-1

CAN/CSA-C22.2 No. 61010-2-101

47 CFR Part 15 Subpart B:1999 + ANSI C63.4-1992