

HiMedia Laboratories Pvt. Ltd.



- We declare that our products, specified under following categories as listed 1. below, comply to and are manufactured according to the requirements of the International Standards as specified in the In Vitro Diagnostic Medical Devices Directive 98/79/EC.
 - Dehydrated Culture Media and Supplements
 - Culture Media Bases
 - Antimicrobial Susceptibility Systems
 - Bacteriological Differential Aids
 - Cell Culture Media
 - Lymphocyte and Granulocyte Separation Media
 - Latex Agglutination Test Kits
 - Epidemiological Screening Kit
- Company or its authorized representative: 2.

Name

: Mr. Federico Pontigia, (Company – Neomed S.R.L.)

Address

: Via G.DI Vittorio, 2-A, 20017 Mazzo Di Rho, MILANO,

ITALY

Phone

: 00-39-02-93900652/93902434

Fax

: 00-39-02-93900968

: neomed@neomed.it

shall fulfill the obligations imposed by in vitro medical device directives as applicable.

- Company undertakes to keep upto date a systematic procedure to review 3. experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature and risk in relation to the product.
- Company undertakes to notify immediately any malfunction/ deterioration of the 4. performance of the product to the appropriate authority and shall recall such products already placed in the market.

For HiMedia Laboratories Private Limited, India

Dated: 15th November, 2011







Fax: (022) 2500 2286

Mumbai - 400 086, India

Via Vadhani Indl. Est., LBS Marg,



HiMedia Laboratories Pvt. Ltd.

15th November, 2011

AGREEMENT & REPRESENTATION

With this letter of agreement and representation, HiMedia Laboratories Private Limited, India, appoints an authorized representative in the EC to represent the company. The details of the authorized representative are given below:

: Mr. Federico Pontigia, (Company-Neomed S.R.L)

: Via G. DI Vittorio, 2-A, 20017 Mazzo Di Rho, MILANO, ITALY

: 00-39-02-93900652/93902434 Phone

: 00-39-02-93900968 Fax Email : neomed@neomed.it

HiMedia Laboratories Private Limited, India shall, through this authorized representative, fulfill all the obligations imposed by the Directive 98/79/EC of the European parliament and of the Council of the European Union on In Vitro Diagnostic Medical devices and ensure that the products of the company meet all provisions of the directives as applicable from time to time.

HiMedia Laboratories Private Limited, India will be responsible for all legal and insurance matters pertaining to our products.

For HiMedia Laboratories Private Limited, India

CEO, Dr. G.M. Warke

I agree to represent HiMedia Laboratories Private Limited, India and be appointed as their EU Representative as per the tenets above.

EU Representative

Name: Mr. Federico Pontigia

NEOMED

Via G. DI VITTORIO, 20017 MAZZO DI RHO (MI) Tel. 02/939.00.652-939.01.463-939.02.434 Fax 02/939.00.968 C.F./P. I. 09580650159 C.C.I.A.A. 1304819 - TRIB. MILANO 291273







Tel.: (022) 4017 9797 / 2500 1607

Fax: (022) 2500 2286