

DECLARATION of CONFORMITY
Non-Annex II Products

Legal Manufacturer's Name: **Remel Inc.**
Legal Manufacturer's Address: 12076 Santa Fe Trail Drive
Lenexa, KS 66215 USA

EDMA Code: 14 02 02 90 00
EDMA Description: Other Manual Identification (Optichin, Bacitracin etc.)

GMDN Code: 33349
GMDN Description: Culture media, single biochemical test

Product Code(s)	Number of Tests	Product Name and Description
R21050	1	Coagulase Plasma 5ml
R21051	1	Coagulase Plasma 15ml
R21052	1	Coagulase Plasma 25ml
R21060	6	Caogulase Plasma

I, the undersigned, hereby declare that the *in vitro* Diagnostic Medical Device(s) described above and bearing the CE marking, conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* Diagnostic Medical Devices.

This declaration is made in accordance with Annex III of the Directive.

Colin Booth

Manufacturer Signature: _____

Full Name (printed): Colin Booth

Title: Global Director, Quality Assurance and Regulatory Affairs

Date: 13 December 2012

Authorized Representative Signature:  _____

Full Name (printed): NANCY COSTARDINO

Title: SENIOR MANAGER - REGULATORY AFFAIRS - EUROPE

Date: 21 Jan 2013