

R911

DECLARATION of CONFORMITY Non-Annex II Products

Legal Manufacturer's Name: Legal Manufacturer's Address: Remel Inc. 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	

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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.

	Whi Borth					
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 CONSTERDING					
Title:	SENIOR MANAGER - REGULATORY AFFAIRS - EUROPE					
Date:	21 Jan 2013					

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