

DECLARATION of CONFORMITY
Non-Annex II Products

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

EDMA Code: 14 01 08 01 00 **EDMA Description:** Gram Stains
GMDN Code: 30650 **GMDN Description:** Gram Stains

Product Code(s)	Number of Tests	Product Name and Description
R40052	250ml	Gram Crystal Violet
R40053	5pk / 250ml	Gram Crystal Violet
R40073	Gallon	Gram Crystal Violet
R40054	250ml	Gram Decolorizer
R40055	5pk / 250ml	Gram Decolorizer
R40075	Gallon	Gram Decolorizer
R40056	250ml	Gram Iodine
R40057	5pk / 250ml	Gram Iodine
R40077	Gallon	Gram Iodine
R40058	250ml	Gram Safranin
R40059	5pk / 250ml	Gram Safranin
R40079	Gallon	Gram Safranin
R40080	4 x 250ml	Gram Stain Kit

I, the undersigned, hereby declare that the *in vitro* Diagnostic Medical Device(s) described above and bearing the CE marking, conform with 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: 17 January 2013

Authorized Representative Signature:  _____

Full Name (printed): NANCY CONSTERDING

Title: SENIOR MANAGER - REGULATORY AFFAIRS - EUROPE

Date: 21 Jan 2013

remel

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