Thermo Fisher Scientific
Microbiology
12076 Santa Fe Trail Drive, P.O. Box 14428
Lenexa, KS 66215
800.255.6730
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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
EU Authorized Representative:	**Thermo Fisher Diagnostics B.V.** Scheepsbouwersweg 1B 1121 PC Landsmeer The Netherlands

EDMA Code:	**EDMA Description:**
14 01 02 90	Other Media in Tubes

GMDN Code:	**GMDN Code:**
58641	Mueller-Hinton broth antimicrobial susceptibility culture medium IVD
58672	Distilled sterile water suspension medium/diluent IVD
58611	Haemophilus species antimicrobial susceptibility culture medium IVD
58661	Sabouraud fungal broth culture medium IVD
58557	Brucella species agar culture medium IVD
58632	Middlebrook Mycobacteria species broth culture medium IVD

Product Code(s)	Number of Tests	Product Name and Description
T3462	N/A	Sensititre Cation Adjusted Mueller-Hinton Broth w/ TES
T3462-05	N/A	Sensititre Cation Adjusted Mueller-Hinton Broth w/ TES (5ml)
T3462-10	N/A	Sensititre Mueller-Hinton Broth Camhb 11ML 10/Box
T34620510	N/A	Sensititre Mueller-Hinton Both w/TES 5ML 10/B
CP112-10	N/A	Sensititre Cation Adjusted Mueller-Hinton Broth w/ TES W/ Lysed Horse Blood
CP114-10	N/A	Sensititre Cation Adjusted AutoRead Mueller-Hinton Broth w/ TES w/ Lysed Horse Blood
T3339	N/A	Sensititre Demineralized Water
T3339-10	N/A	Sensititre Demineralized Water 10/pk
T3470	N/A	Sensititre HTM Broth
Y3462	N/A	Sensititre YeastONE Broth
T3450	N/A	Sensititre Supplemental Brucella Broth
T3493	N/A	Sensititre Demineralized Water with Glass Beads
T8006	N/A	Sensititre Cation Adjusted Mueller-Hinton w/ TES w/ OADC

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Product Code(s)	Number of Tests	Product Name and Description
T3491	N/A	Sensititre Saline - Tween w/ Glass Beads
T3441	N/A	Sensititre Middlebrook 7H9 Broth w/ OADC

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.

Manufacturer Signature: Gary Klaassen

Full Name (printed): Gary Klaassen

Title: Director, Quality Assurance & Regulatory Affairs

Date: November 13, 2020