

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

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



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

