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Microbiology
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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<br>Lenexa, KS 66215<br>USA |
| EU Authorized Representative: | **Thermo Fisher Diagnostics B.V.**<br>Scheepsbouwersweg 1B<br>1121 PC Landsmeer<br>The Netherlands |

| **EDMA Code:** | **EDMA Description:** |
|---|---|
| 14 02 02 06 00 | Haemophilus & Neisseria – Manual |
| 14 02 02 05 00 | Anaerobes – Manual |
| 14 02 02 03 00 | Streptococci – Manual |
| 14 02 02 | Biochemical Identification – Manual |
| 14 02 02 02 00 | Non-fermenters – Manual |
| 14 02 02 01 00 | Enterobacteriaceae – Manual |
| 14 03 04 01 | Identification Systems for Yeasts – Manual |
| 14 02 02 | Biochemical Identification - Manual |
| 14 02 02 0400 | Staphylococci – Manual |

| **GMDN Code:** | **GMDN Code:** |
|---|---|
| 50423 | Multiple Haemophilus/Neisseria species culture isolate identification IVD, kit |
| 50413 | Multiple anaerobic bacteria species culture isolate identification IVD, kit |
| 62908 | Multiple urinary tract pathogen culture isolate identification IVD, kit, rapid |
| 50421 | Multiple non-Enterobacteriaceae species culture isolate identification IVD, kit |
| 50415 | Multiple Enterobacteriaceae species culture isolate identification IVD, kit |
| 30666 | Multiple candida/yeast species culture isolate identification IVD, kit |
| 51656 | Multiple Staphylococcus bacterial species culture isolate, IVD, kit |

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| Product Code(s) | Number of Tests | Product Name and Description |
|---|---|---|
| R8311001 | 20 | RapID NH System |
| R8311002 | 20 | RapID ANA II System |
| R8311003 | 20 | RapID STR System |
| R8311004 | 20 | RapID SS/u System |
| R8311005 | 20 | RapID NF Plus System |
| R8311006 | 20 | RapID ONE System |
| R8311007 | 20 | RapID Yeast Plus Panel |
| R8311008 | 20 | RapID CB Plus |
| R8311009 | 20 | RapID Staph Plus |

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: December 9, 2020