

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 747791 R000

Manufacturer: Remel, Inc.

Address:

12076 Santa Fe Trail Drive
Lenexa
Kansas
66215
USA

Single Registration Number: Not available

EU Authorised Representative: Thermo Fisher Diagnostics B.V.

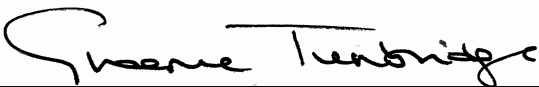
Address:

Scheepsbouwersweg 1B,
1121 PC Landsmeer,
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-08-07**

Current Issue Date: **2023-08-07**

Starting Validity Date: **2023-08-07**

Expiry Date: **2028-08-06**

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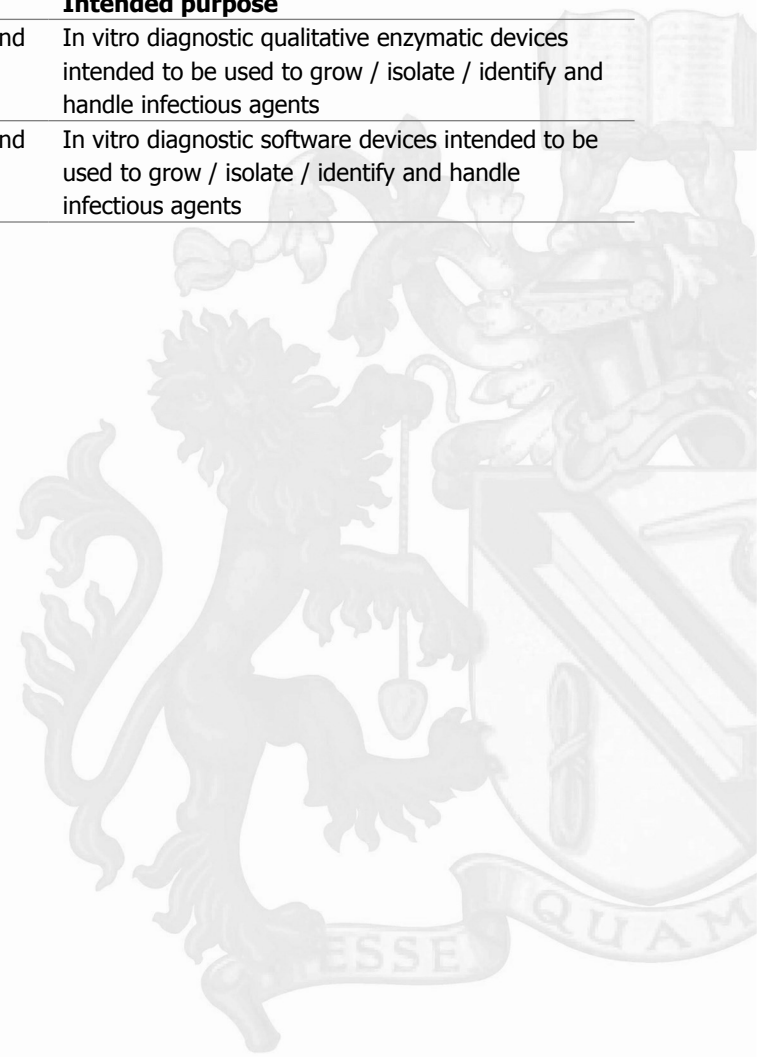
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Device Schedule: Class D, C and B devices

Class B devices	Intended purpose
IVR 0505 – Devices intended to be used to grow / isolate / identify and handle infectious agents	In vitro diagnostic qualitative enzymatic devices intended to be used to grow / isolate / identify and handle infectious agents
IVR 0505 – Devices intended to be used to grow / isolate / identify and handle infectious agents	In vitro diagnostic software devices intended to be used to grow / isolate / identify and handle infectious agents



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3414852	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.