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***Note to file***
***Note au dossier***

| Application Information / Information de soumission | |
|---|---|
| *Licence Name/Nom de l'homologation:<br>**ELECSYS ANTI-SARS-COV-2** | Application Number/Numéro de soumission<br>**314982** |
| Licence # / # de l'homologation:<br>**0** | Application Type/Type de soumission:<br>**Interim Order** |
| Manufacturer/Fabricant:<br>**ROCHE DIAGNOSTICS GMBH** | Company ID/Identificateur d'entreprise:<br>**114999** |
| Risk Class:<br>**3** | Rationale:<br>**Classification Rule IVDD Rule 2(b)(i)** |
| *Licence Type/Type d'homologation:<br>**Test Kit** | Rationale: |

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

**Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2.**
**The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.**

| OEM Licence Information | |
|---|---|
| OEM Licence Name : | OEM Manufacturer : |
| OEM Intended Use and/or Indications for Use | |

| Reason for Change | | Comment(s) |
|---|---|---|
| Change to classification of a device | ☐ | |
| Manufacturer name change | ☐ | |
| License name change | ☐ | |
| Device name change | ☐ | |
| Change to the purpose/indication of license | ☐ | |
| Addition of device(s) | ☐ | |
| Deletion of device(s) | ☐ | |

| Reason for Change | | Comment(s) |
|---|---|---|
| Change in name and/or address of the Private Label Manufacturer | ☐ | |
| Private Label License name change | ☐ | |
| Private Label Device name change | ☐ | |
| Addition of device(s) | ☐ | |
| Deletion of device(s) | ☐ | |

***Certificate Screening Checklist:***

| Cert # (new): | Cert Revisions / Comments (If Applicable): |
|---|---|
| | |

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| | |
|---|---|
| Cert. # (old): | |
| Replacing Existing Cert on File (Y/N): | |

| Criteria | conforms | Comments/info for MDS |
|---|---|---|
| Issued to full name of manufacturer as it appears on application/licence and label. | ☐ | |
| Issued to complete civic address matching application/licence and label. | ☐ | |
| Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282 | ☐ | |
| Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution. | ☐ | |
| Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices. | ☐ | |
| Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers. | ☐ | |
| Auditing Organisation is Authorized or Recognized | ☐ | |
| Statement of Authorization or Recognition. | ☐ | |
| Field labelled “Effective Date” | ☐ | |
| Field labelled “Expiry Date” | ☐ | |
| Validity period ≤ 3 years | ☐ | |
| Unique identification code labelled “certificate number” or “certification document number” | ☐ | ☐ new ☐ revised |
| Name, title, and signature of certification authority | ☐ | |
| Pagination (page x or y) included on all pages . All pages present. | ☐ | |
| Method to verify validity | ☐ | |

| **Screening Decision** | |
|---|---|
| **Accept** | |
| **Jiazhen Minnie Dai**<br>Device Licensing Services Division<br>Medical Devices Bureau | **Date**:2020-05-01 |

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Check GMDN

| GMDN Name | GMDN Code | GMDN Description | Issue | Action for Screener | Regulatory Action | Reference Material |
|---|---|---|---|---|---|---|