



| Application Information / Information de soumission   |  |
|---|--|
| *Licence Name/Nom de l'homologation:<br><b>XPert XPRESS SARS-COV-2</b>  | Application Number/Numéro de soumission<br><b>312836</b> |
| Licence # / # de l'homologation:<br><b>0</b>  | Application Type/Type de soumission:<br><b>U</b>         |
| Manufacturer/Fabricant:<br><b>CEPHEID</b>   | Company ID/Identificateur d'entreprise:<br><b>114687</b> |
| Risk Class:<br><b>3</b>   | Rationale:<br><b>IVDD Rule 2(b)(i)</b>                   |
| *Licence Type/Type d'homologation:<br><b>Test Kit</b>   | Rationale:   |
| <input type="checkbox"/> Contains Controlled Substance(s) <input type="checkbox"/> Contains Drug(s) <input type="checkbox"/> Contains Biological Material(s)  |  |
| *Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications<br>The Xpert Xpress SARS-CoV-2 test is a rapid test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens collected from individuals who meet CDC criteria for SARS-CoC-2 testing. |  |

Note: Emergency Use Authorization Request. No IO Authorization Form.

| Screening Decision   |                                |
|--|--------------------------------|
| <b>Deficient</b>   |                                |
| <b>Marie Rochefort</b>                                       | <b>Date:</b><br>March 23, 2020 |
| Device Licensing Services Division<br>Medical Devices Bureau |                                |

| COVID-19 Medical Device & Manufacturer Details |   |
|--|---|
| Class of Device                                | Class III   |
| Intended Use of Device (Section 4(1)(f))       | The Xpert Xpress SARS-CoV-2 test is a rapid test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens collected from individuals who meet CDC criteria for SARS-CoC-2 testing. |

| Device Name            | Identifier      | GMDN Code | PNC Code |
|------------------------|-----------------|-----------|----------|
| XpertXpress SARS-CoV-2 | XPRSARS-COV2-10 | 88UJH     | 64747    |
|                        |                 |           |          |
|                        |                 |           |          |
|                        |                 |           |          |



*Note to file*  
*Note au dossier*

Check GMDN

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