



Licence Number

**16502**

Numéro de la licence

**Medical Device  
Establishment Licence**

**Licence d'établissement  
pour les instruments médicaux**

**WRAP-TITE INC.**

6200 COCHRAN ROAD  
OLON, OHIO  
UNITED STATES  
44139

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

|                        | Distributor / Distributeur | Importer / Importateur | Manufacture Devices for Distribution /<br>Fabricant d'instruments médicaux pour<br>distribution |
|------------------------|----------------------------|------------------------|-------------------------------------------------------------------------------------------------|
| Class I / Classe I     | No / Non                   | No / Non               | No / Non                                                                                        |
| Class II / Classe II   | Yes / Oui                  | No / Non               |                                                                                                 |
| Class III / Classe III | No / Non                   | No / Non               |                                                                                                 |
| Class IV / Classe IV   | No / Non                   | No / Non               |                                                                                                 |

**Attestation made :**

**Attestations faites :**

|                                                                                                                                                                                                                                                                                                                              |                                                                      |                                                                                                                                                                                                                                                                                                                                                                |
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| The establishment has documented procedures in place in respect of: <ul style="list-style-type: none"><li>distribution records</li><li>complaint handling</li><li>recalls</li><li>mandatory problem reporting</li><li>handling, storage, delivery</li><li>installation</li><li>corrective action</li><li>servicing</li></ul> | [ Y ]<br>[ Y ]<br>[ Y ]<br>[ N ]<br>[ Y ]<br>[ N ]<br>[ Y ]<br>[ Y ] | L'établissement a mis en oeuvre une procédure écrite concernant: <ul style="list-style-type: none"><li>les registres de distribution</li><li>les plaintes</li><li>les rappels</li><li>rapports d'incident obligatoires</li><li>la manutention, le stockage, la livraison</li><li>l'installation,</li><li>les mesures correctives</li><li>l'entretien</li></ul> |
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cette page**

Issue Date, date de délivrance: 2021-06-03

|                                            |                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Minister of Health<br>Ministre de la santé | Countersigned: Director, Medical Devices Compliance Program or delegated authority<br>Contresigné par: Directrice, Programme de la conformité des matériels médicaux ou autorité déléguée<br><br><br>Chad Sheehy |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.  
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.



## Sites

WRAP-TITE INC.  
6200 COCHRAN ROAD  
OLON, OHIO  
UNITED STATES  
44139

Company ID

164222

No. d'identification  
de la société