Certificate of Analysis

[To be printed on Letterhead of Manufacturer]

Name and Address of Manufacturer
< Please add Manufacturer Name >
< Please add Manufacturer Address >

We hereby declare that methods of analysis applied on the medical device *< Please add product name (without listing codes/catalogue numbers unless needed to identify the product) as it appears in the Free Sale Certificate / CFG / Canadian Medical Device Active License>* **are according to manufacturing standards and under the manufacturer responsibility.**

We confirm that the product meets its defined specifications and has passed the tests according to applicable relevant standards as per below tables:

< Please fill in the below table >
< Please mention "Not Applicable" for properties category that is not applicable on the product >
< Please attach a copy of release certificate / certificate of analysis / certificate of conformance for any batch of a representative code/catalogue number >

Specification *(Please describe the defined specification and any applicable limit as per each properties category)*	**Test / Process Validation** *(Please clarify the test or process validation applied on the product to confirm the defined specification)*	**Applicable standard** *(Please clarify the applicable standard)*
Physical properties		
Chemical properties		
Biological properties		

Additional applied standards: *< Please fill in the below table where applicable as per the mentioned example>*

Applied Standard	***Standard Description***
ISO 14971:2019	Application of risk management to medical devices

Signed on behalf of *< Please add manufacturer name >***,**

Authorised signatory:		
< please add authorised signatory name and title >	*< Please apply signature and manufacturer stamp >*	*< Please add date of applying signature>*
Name & Position	**Signature & Stamp**	**Date**

- Lines in blue are for clarification purpose only and to be deleted in the signed document.
- Wording in green between marks " " may be used where applicable.