

## 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<br>(Please describe the defined specification and any applicable limit as per each properties category ) | Test / Process Validation<br>(Please clarify the test or process validation applied on the product to confirm the defined specification) | Applicable standard<br>(Please clarify the applicable standard) |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| <b>Physical properties</b>                                                                                             |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |
| <b>Chemical properties</b>                                                                                             |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |
| <b>Biological properties</b>                                                                                           |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |
|                                                                                                                        |                                                                                                                                          |                                                                 |

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.