[Printed on letterhead]

**BIOCOMPATIBILITY STATEMENT**

(Include the name of the medical device to be registered)

**Raw materials and Patient contacting**

|  |  |  |
| --- | --- | --- |
| Raw Material  | Direct contact with the patient | Contact duration[[1]](#footnote-1) |
| Include the raw material involved in the manufacture of the medical device, including the alloy and the applicable standards For example:X20Cr13 (AISI420A)Silicone (handles) | Provide information about if the raw material is in direct contact with the patient or not For example:Yes No | For exampleLimited (<24h) |

 Signature

[Position]

[Company]

1. Contact according to ISO 10993-1 [↑](#footnote-ref-1)