[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 example  Limited (<24h) |

Signature

[Position]

[Company]

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