# APPENDIX V: APPLICATION FORM FOR VARIATION / ALTERATION OF A REGISTERED SURGICAL INSTRUMENT/APPLIANCES

***Regulation Section 39***

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| File Number:\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Registration Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Product Name: | |
| Risk Class of Surgical Instrument/Appliance: | |
| Category of Surgical Instrument/Appliance: | |
| Model/Series/System if applicable: | |
| Type of change(State type of variation/amendment) |  |

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| **Other application(s):**  (Provide brief information on any ongoing variation / amendment or other variation(s) / amendment(s) / alterations submitted in parallel or renewal of applications or line extension(s)). |
| **Scope** (Please specify scope of change(s)/ variations/amendment(s) in a concise way) |
| **Background** for change and justification for consequential change(s) (If applicable), give brief background explanations for proposed changes to the authorized/registered product as well as justification in case of consequential changes. |

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| **Present**  (Specify precise present wording) | **Proposed**  (Specify precise proposed variation/amendment/alteration/change) |

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| In case of change to the surgical instrument / appliance(s) detail, package leaflet, Instruction for use (IFU) or catalogue applications should always enclose a working model clearly showing the differences between the proposed new version and the current text, previous or reference text. |
| Particulars of the applicant (Holder of registration Certificate)  Name: ....................................................................................................................  Physical address: ..................................................................................................  Postal address (if different):  Phone: ………………………Fax: …………………e-mail:............................... |
| **Declaration of the applicant:**  I hereby submit an application of the above registered product to be amended/varied/altered in accordance to the proposals given above. I declare that (Please tick)   1. There are no other changes other than those identified in this application(s) except for those addressed in the variation/amendment submitted in parallel; such parallel variations/amendments have to be specified under other application(s) 2. Where applicable , variation fees have been paid; 3. Change will be implemented from next run/next printing   Name:  Qualification:  Position in the Company:  Signature:  Date |