

I. SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

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| I.1 | I hereby confirm that /confirm on behalf of the sponsor (delete which is not applicable) that: <ul style="list-style-type: none">• the information provided is complete;• the attached documents contain an accurate account of the information available;• the clinical trial will be conducted in accordance with the protocol; and• the clinical trial will be conducted, and SUSARs and result-related information will be reported, in accordance with the applicable legislation. |
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| I.2 | APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY (as stated in section C.1): |
| I.2.1 | Date: 25 AUG 2016 |
| I.2.2 | Signature ³¹ :  |
| I.2.3 | Print name: T. VERSCHOORE |

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| I.3 | APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE (as stated in section C.2): |
| I.3.1 | Date: |
| I.3.2 | Signature ³² : |
| I.3.3 | Print name: |