

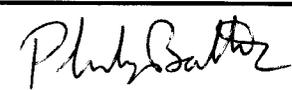
**I LIST OF THE DOCUMENTS APPENDED TO THE NOTIFICATION FORM (cf. Section 3.7 of detailed guidance CT-1)**

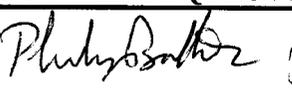
Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es).

<b>I.1 Cover letter</b>	<b>YES</b>
<b>I.2 Extract from the amended document in accordance with Section 3.7.c. of detailed guidance CT-1 (if not contained in Part F of this form)</b>	<input type="checkbox"/>
<b>I.3 Entire new version of the document<sup>11</sup></b>	<input type="checkbox"/>
<b>I.4 Supporting information</b>	<input type="checkbox"/>
<b>I.5 Revised .xml file and copy of initial application form with amended data highlighted</b>	<b>YES</b>
<b>I.6 Comments on any novel aspect of the amendment if any</b>	

**J SIGNATURE OF THE APPLICANT IN THE MEMBER STATE**

<b>J.1</b>	I hereby confirm on behalf of the sponsor that <ul style="list-style-type: none"><li>• The above information given on this request is correct;</li><li>• The trial will be conducted according to the protocol, national regulation and the principles of good clinical practice; and</li><li>• It is reasonable for the proposed amendment to be undertaken.</li></ul>
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<b>J.2</b>	<b>APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY (as stated in section D.1):</b> <b>YES</b>
J.2.1	Signature <sup>12</sup> : 
J.2.2	Print name: PHILIP BAHR
J.2.3	Date: 27/2/13

<b>J.3</b>	<b>APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE (as stated in section D.2):</b> <b>YES</b>
J.3.1	Signature <sup>13</sup> : 
J.3.2	Print name: PHILIP BAHR
J.3.3	Date: 27/2/13

<sup>11</sup> Cf. Section 3.7.c. of the detailed guidance CT-1.

<sup>12</sup> On an application to the Competent Authority only, the applicant to the Competent Authority needs to sign.

<sup>13</sup> On an application to the Ethics Committee only, the applicant to the Ethics Committee needs to sign.