Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**2014-001005-41**
B.2 Sponsor's protocol code number:	**fluresstudy**
B.3 Full title of the trial : Evaluation of FLuid REsuscitation with Sterofundin ® ISO (Ringerfundin),	
B.4 or NaCl 0.9%. (FluReS study)	

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	■
C.1.1	Sponsor	■
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below:**	
C.1.4.1	Organisation : Ghent University Hospital	
C.1.4.2	Name of person to contact : Lieselot Burggraeve	
C.1.4.3	Address : De Pintelaan 185, 9000 Ghent	
C.1.4.4	Telephone number : +32 9 3320907	
C.1.4.5	Fax number : +32 9 332 05 20	
C.1.4.6	E-mail: bimetra.clinics@uzgent.be	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
•	Co-ordinating investigator (for multicentre trial):	☐
•	Principal investigator (for single centre trial):	☐
C.2.5	**Complete below :**	
C.2.5.1	Organisation:	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	2016/01/29

D.2	**Is it an early termination?[3]**	yes ☐ no ■

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

2 According to national legislation.

3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1	If yes, give date (YYYY/MM/DD):
D.2.2	Briefly describe in an annex (free text):
D.2.2.1	The justification for early termination of the trial;
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that~~/confirm on behalf of the sponsor that~~ (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)
E.2.1	Date : 25 Apr 2017
E.2.2	Signature :
E.2.3	Print name: Lieselot Burggraeve

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:** ☐
E.3.1	Date :
E.3.2	Signature :
E.3.3	Print name:

[4] Section 4.3. of the detailed guidance CT-1.