



## **EC Declaration of Conformity**

We Perinatal Institute of 75 Harborne Road, Birmingham, United Kingdom, B15 3BU

(Companies House 08466773)

in accordance with the following directive(s) and guidance

Council Directive 93/42/EC (concerning medical devices)

Directive 2007/47/EC (amendment to Directive 93/42/EC) MEDDEV 2.4/1 Rev. 9 (Classification of medical devices)

MEDDEV 2.1/6 (Qualification and Classification of stand alone software)

hereby declare that

GROW Service (GROW-Centile, GROW-App, GROW-API)

conform with the applicable requirements above, and that the following evidence:

Registration with the Medicines & Healthcare products Regulatory Agency

**Technical Information and Specifications** 

Risk Assessment and Mitigation

Clinical Evidence of Effectiveness

is available for public and Competent Authority review at

https://www.perinatal.org.uk/CE/GrowService

Medicines & Healthcare products Regulatory Agency registration number:

CA015106

Signed:

Name Professor Jason Gardosi Ian Bird

Position Director IT Manager

**On** 20 October 2015 20 October 2015