

MDOC: 010

Revision No: 02

Declaration of Conformity

We **Bio-Medical Research Ltd.**
Parkmore Business Park West
Galway, Ireland.


Declare under our sole responsibility that the devices:

Femifree/Innovo Type: *207*

to which this declaration relates, are in conformity with the Annex I of
the European Directive:

93/42/EEC

“Council Directive of 14 June 1993 on the approximation of the laws of
the Member States concerning medical devices”.

Signature:  Date: 26 - JAN - 2016
Brendan McCormack

Title: ***Quality Manager***

Location: Bio-Medical Research Ltd.
BMR House, Parkmore Business Park West, Galway, Ireland

Declaration valid until: **23 January 2021**

EC Certificate No. CE 638241

Full Quality Assurance System, Directive 93/42/EEC on Medical Devices, Annex II (excluding Sect. 4)

BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP

Notified Body Number: 0086

Form 523, Issue 08, CCN 16307

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Revision History

Revision	Date	CCN	Description of Change	Changed By
01	15 January 2015	N/A	Create Document	Anne-Marie Keenan
02	26 January 2016	16311	Update of BSI Certificate and addition of CCN number for release	Anne-Marie Keenan