

MDOC:001

Revision No: 01

Declaration of Conformity

We **Atlantic Therapeutics Ltd.**
Parkmore Business Park West
Galway, Ireland.

Declare under our sole responsibility that the device to which this declaration relates;

Innovo, Type Number 207

is 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"

Classification/Rule: Class IIa, Rule 9 according to Annex IX

We declare that the above-mentioned device meets the provisions of the Council Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("ROHS2").

Signature:  Date: 29-JAN-2018
Brendan McCormack

Title: VP of Quality, Regulatory and Clinical

Location: Atlantic Therapeutics Ltd.
Parkmore Business Park West, Galway, Ireland

Declaration valid until: 2023-01-24

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Revision History

Revision	Date	CCN	Description of Change	Changed By
Draft	16-Jan-18	N/A	Initial Draft	Anne-Marie Keenan
01	29-Jan-18	18-012	Release Document	Anne-Marie Keenan