



Atex Co.,Ltd.

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EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of ATEX Co., Ltd. We herewith declare that the under-mentioned products are in conformity with the general safety and performance requirements and provisions of Regulation (EU) 2017/ on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Product Name: **Power Spiral Tape**

Model Name: **Power Spiral tape A, Power Spiral Tape B, Power Spiral Tape C and OEM Brands**

Classification: **Class I based on Rule 1, Annex VIII, Regulation (EU) 2017/745**

Conformity Assessment Route: **Annex IX, Regulation (EU) 2017/745 on medical devices**

Standards applied: **EN ISO 13485:2016/AC:2016, EN ISO14971:2012, EN ISO10993-1:2018, EN 1041:2008/ A1:2013, EN 62366-1:2015, EN ISO 15223-1:2016, MEDDEV 2.7/1 [Rev. 4] :2016, EN ISO 10993-5:2009, EN ISO 10993-10:2010, MEDDEV 2.12/1 [Rev.8]: 2013, MEDDEV 2.12/2 [Rev.2] :2012**

EC Representative: **Meridius Medical Europe Ltd.**

**Unit 3D, North Point House, North Point Business Park, New Mallow Road,
Cork, T23 AT2P, Ireland**

EC Certificate: **ATEX-PST-003**



Place of Issue : **Gyeonggi-do, Korea**

Date of Issue : **Start of CE Marking**

Signature :

Kim Hae Ryong / President

A handwritten signature in blue ink, appearing to read "Kim Hae Ryong".