

EC Declaration of Conformity

Issue Date: 2017/10/2

The manufacturer

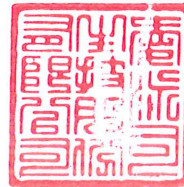
Name: A Plus Biotechnology Company Limited
Address: 2F.-2, No.120, Qiaoh Rd., Zhonghe Dist., New Taipei City, Taiwan

is hereby solely responsible for making the declaration that

Product name: APS Orthopedics Manual Surgical Instrument (Non-Sterile)
Classification: I (Rule 6)

listed above conform to the following requirements:

Regulation(s): Council Directive 93/42/EEC on medical devices, as amended
Module: Annex VII excluding Section 5 and 6 (Module A)
Standard(s): EN 980:2008
EN 1041:2008
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 13485:2012
EN ISO 14971:2012
EN ISO 17665-1:2006
EN ISO 14630:2009



General Manager

Andy Lo

(Position/Title)

(Name)

(Signature)

(Date)

Andy Lo 2017, 10, 2