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9th February 2022

RE: Instructions for Use

To whom it may concern,

Instructions for use are not required for Class I or Class IIa device as identified in the Medical Device Regulation (MDR 2017/745) concerning medical devices of which we comply in order to CE mark our devices.

The statement in Annex I – General Safety and Performance Requirements – Section 23.1 (d) states:

"Instructions for use shall be provided together with devices. By way of exemption, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section."

For and on behalf of Swann-Morton Ltd

Darren Hall
QA/RA Systems Manager