



UK DECLARATION OF CONFORMITY

Manufacturer: Osseointegration International BV
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List of Class I (non-sterile)* products that are covered under this declaration:

*According to Annex IX of Directive 93/42 rule 1;

<i>Device</i>	<i>Description</i>
GV18	Osseointegration torque adapter
GV19	Osseointegration torque adapter
GV20	Osseointegration torque adapter
GV21	Osseointegration torque adapter

<i>Device</i>	<i>Description</i>
OPL LLC toolkit	Toolkit for GV connector family

We hereby declare that above mentioned products meets all applicable requirements of Part II of the UK Medical Device Regulation 2002 (UK). Osseointegration International BV bears full responsibility for the above products and declares to supply Easy Medical Devices with any information requested by them to enable regulatory compliance.

Common specifications

- ISO 13485:2016 Medical devices - Quality Management systems - Requirements for regulatory purposes
- ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- 14971:2019 Medical devices – Application of risk management to medical devices

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Place: Ruurlo, The Netherlands

Signature:

Frans Verhaegh
Managing Director