



AU DECLARATION OF CONFORMITY

Manufacturer: Osseointegration International BV
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Netherlands

AU Representative: Osseointegration International Pty Ltd
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List of Class I (non-sterile, non-measuring) devices that are covered under this
declaration:

<i>Device</i>	<i>Description</i>	<i>GMDN</i>
GV18	Osseointegration torque adapter	61229
GV19	Osseointegration torque adapter	61229
GV20	Osseointegration torque adapter	61229
GV21	Osseointegration torque adapter	61229

<i>Device</i>	<i>Description</i>	<i>GMDN</i>
OPL LLC toolkit	Toolkit for GV connector family	64717

We hereby declare to have reviewed Part 6 of Schedule 3 of the Regulations and the devices comply with all applicable provisions of those procedures. The devices also comply with the relevant essential principles as set out in Schedule 1 and 2 of the Regulations. The technical documentation will be updated whenever changes are made in relation to the devices.

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