OSSEOINTEGRATION
international

EC DECLARATION OF CONFORMITY

Manufacturer: Osseointegration International B.V.
Spoorstraat 9 | 7261AE | Ruurlo
The Netherlands
Tel.: +31 573 451 945
E-mail: nick.peters@osseointernational.com

SRN: NL-MF-000007838

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

*According MDR (EU) 2017/745 ANNEX VIII Rule 1;

BASIC UDI-DI: 8720589951GVFAMILYLY	
Device / Product / Trade name	*Description*
GV18	Osseointegration torque adapter
GV19	Osseointegration torque adapter
GV20	Osseointegration torque adapter
GV21	Osseointegration torque adapter

BASIC UDI-DI: 8720589951OPLLLCTOOLKIT63	
Device / Product / Trade name	*Description*
OPL LLC toolkit	Toolkit for GV connector family, also known as **Sleeve Extractor Toolkit** and **1009043**

We hereby declare that above mentioned products meets all applicable requirements of the EU Medical Device Regulation 2017/745 as well as all other applicable local regulations. This declarations is issued under the sole responsibility of the manufacturer;

Common specifications

- ISO 13485_2016 (en) Medical devices - Quality Management systems - Requirements for regulatory purposes
- ISO 15223-1:2016(Cor. 2017-04) (en) Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- NEN-EN 1041:2008+A1:2013 (en) Information supplied by the manufacturer with medical devices
- 14971:2019 (en) Medical devices – Application of risk management to medical devices

Date issued: 06-06-2023
Place: Ruurlo, The Netherlands

Signature:

Frans Verhaegh
Managing Director