

Declaration of Conformity
Technical Documentation Technical File #1M, Revision 59

Manufacturer:

Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Notified Body:

BSi
Identification Number: 2797

Full Quality Assurance Certificate CE 552745

Products:

See Attached

Classification:

Class IIb, Rule 8 of Annex IX of the MDD 93/42/EEC

Start of CE Marking:

See Attached

Conformity Assessment Route:

MDD Annex II Section 3.2 excluding Section 4

We declare that the above-mentioned products meet the provisions of the legislation transposing
European **Medical Devices Directive 93/42/EEC**
concerning Medical Devices into the laws of the European Economic area.
All supporting documentation is available under the premises of the manufacturer.

Mitchihiro Ohiwa / DePuy Spine, Inc.
Director, Regulatory Affairs

DD/MM/YYYY

Nicolas Hainard/ Medos International SARL
Director QA Medos International Sàrl

DD/MM/YYYY