

Name and address of the firm: **AXIS biodental SA**
 Les Rosées 5,
 CH-2336 Les Bois
 Suisse

By the present document, AXIS biodental SA declare under our sole responsibility that the following products

Product Family: AXIS Dental Implants System

Model

| Reference | Designation | Class according to annex IX of directive 93/42/EEC | Meet all provisions of the 93/42/EEC Directive according to the |
|-----------|-----------------------|--|---|
| A1074 | Monobloc M8 | IIb | Annex II, excluding Section 4 |
| A1075 | Monobloc M10 | IIb | |
| A1076 | Monobloc M12 | IIb | |
| A1078 | Hexalobe M8 | IIb | |
| A1079 | Hexalobe M10 | IIb | |
| A1080 | Hexalobe M12 | IIb | |
| D1154 | Straight abutment | IIb | |
| D1155 | 15° angled abutment A | IIb | |
| D1157 | 15° angled abutment B | IIb | |
| D1149 | Prosthetic screw | IIb | |
| D1165 | Holistic screw | IIb | |
| D1048 | Healing abutment H2.5 | IIa | |
| D1132 | Healing abutment H4.0 | IIa | |
| D1131 | Temporary abutment | IIa | |
| D1153 | Cover screw | IIa | |
| D1171 | Cover cap | IIa | |

Notified body

*DNV GL Nemko Presafe AS. Notified body n°2460
 Certificate n°233179-2017-CE-ITA-NA-PS Rev. 0.0
 Valid until: 30th June 2021*

Les Bois, 27th October 2017

Director
 Jean-Paul Berclaz