

STATEMENT – CUSTOM MADE DEVICE ANNEX VIII

Statement in accordance with Annex VIII of the Belgian law “Koninklijk besluit betreffende Medische Hulpmiddelen of 18 March 1999” and the Directive on Medical Devices (93/42/EEC) and amendments

MANUFACTURER

DENTSPLY Implants nv
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Belgium

PRODUCT NAME

Atlantis® suprastructures

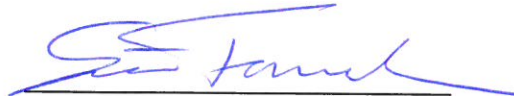
Atlantis® Bar
Atlantis® Bridge
Atlantis® Hybrid
Atlantis® 2in1
(as listed in Annex)

The Atlantis suprastructures are metallic dental restorative devices which are intended for attachment by screw retention to dental implants to aid in the treatment of partially and totally edentulous patients for the purpose of restoring chewing function.

The products in the scope of this statement are custom made by order of a medical practitioner or other authorized person and intended to be exclusively used for the patient identified in the prescription form.

The products conform to the relevant requirements of the Medical Device Directive 93/42/EEC and amendments including the essential requirement listed in Annex I.

As the manufacturer within the European Economic Community, we hereby certify that the product(s) listed are in conformance with the provisions set out in the directive and the national law stated above.



Göran Forsmalm
Manager Regulatory Affairs
Platform Lead Digital Implant Solutions

ANNEX

Item No.	Product Description
36302-x x = 2 – 15	Atlantis Bar Ti 2 to 15 implants
36306-x x = 2 – 15	Atlantis Bar CoCr, 2 to 15 implants
36402-x x = 2 – 15	Atlantis Bridge Ti 2 to 15 implants
36406-x x = 2 – 15	Atlantis Bridge CoCr 2 to 15 implants
36412-x x = 2 – 15	Atlantis Bridge Ti AM 2 to 15 implants Additive Manufacturing (AM)
36416-x x = 2 – 15	Atlantis Bridge CoCr AM 2 to 15 implants Additive Manufacturing (AM)
36452-x x = 2 – 15	Atlantis Hybrid Ti 2 to 15 implants
36456-x x = 2 – 15	Atlantis Hybrid CoCr 2 to 15 implants
36462-x x = 2 – 15	Atlantis Hybrid Ti AM 2 to 15 implants Additive Manufacturing (AM)
36466-x x = 2 – 15	Atlantis Hybrid CoCr AM 2 to 15 implants Additive Manufacturing (AM)
36352-x x = 3 – 15 (x = 0)	Atlantis 2in1 Hybrid Ti 3 to 15 implants (Duplicate Secondary Hybrid)
36362-x x = 3 – 15 (x = 0)	Atlantis 2in1 Bridge Ti 3 to 15 implants (Duplicate Secondary Bridge)



Revision History

Document Version	Change note / Description	PCO No
(00	Former revisions)	-
01	Addition of Additive Manufacturing (Ti)	-
A	Replaces version 01 Addition of compatibility with ATIS Multibase Abutment EV	-
B	Removal of reference 36302-16 (ATLANTIS suprastructure, bar Ti, 16 implants)	-
C	Removal of references 36352-2 (Atlantis 2in1 Hybrid Ti, 2 implants) and 36362-2 (Atlantis 2in1 Bridge Ti, 2 implants)	-
D	Addition of new Atlantis suprastructure interfaces for compatibility with more abutments and implants (GIPA # 2500)	-
E	Harmonisation of the Product Acceptance Criteria for milled suprastructures	RPT-00069420
F	Addition of new Atlantis suprastructure interface for compatibility with Bredent SKY uni.cone abutment	RPT-00076834