Dentsply Sirona Implants

STATEMENT – CUSTOM MADE DEVICE
ANNEX VIII

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

MANUFACTURER

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PRODUCT NAME

Atlantis® Conus Structures:
Atlantis® Conus Base
Atlantis® Conus Bridge
Atlantis® Conus Hybrid
(as listed in Annex)

The Atlantis Conus suprastructures are metallic dental restorative devices which are intended for attachment to Atlantis® Conus Abutments, Overdenture via prefabricated SynCone® 5° Taper caps (Degulor®) in the treatment of partially or totally edentulous jaws 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

Dentsply Sirona Implants

ANNEX

Item No.	Product Description
36331	Atlantis Conus Base Ti
36332	Atlantis Conus Hybrid Ti
36333	Atlantis Conus Bridge Ti

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REVISION HISTORY

Document Version	Change note / Description	PCO No
A	First issue	-
B	Update of dimensional parameter (stick-out length)	RPT-00070757