Dentsply Sirona Implants

STATEMENT – CUSTOM MADE DEVICE
ANNEX VIII

Statement in accordance with the Act (1993:584) Medical Devices, LVFS 2003:11 and the Directive on Medical Devices (93/42/EEC) and amendments

MANUFACTURER

DENTSPLY IH AB
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PRODUCT NAME

Atlantis® Abutment Insertion Guide
(as listed in Annex)

The Atlantis® Abutment insertion guide is intended for use with single or multiple Atlantis® Abutments (for cement-retained restorations) during clinical installation. It is intended to be used to ensure the correct abutment/implant relation.

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 DIS

Dentsply Sirona Implants

ANNEX

Item No.	Product Description
35030	Atlantis Abutm Ins Guide
35030M	Atlantis Abutm Ins Guide M
35030MR	R Atlantis Abutm Ins Guide M
35030R	R Atlantis Abutm Ins Guide

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REVISION HISTORY

Document Version	Change note / Description	PCO No
A	Replaces DC-DI-S002:A located in WIP Document	