



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
Box 14
431 21 Mölndal, Sweden

PRODUCT NAME

Atlantis® Abutment
Atlantis® Crown Abutment
Atlantis® Conus Abutment
Atlantis® Crown
(as listed in Annex)

The Atlantis® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for support single and multiple tooth prosthesis in mandible or maxilla. The abutment screw is intended to secure the Atlantis® Abutment to the endosseous implant.

The Atlantis® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patient. The abutment screw is intended to secure the Atlantis® Crown Abutment to the endosseous implant.

The Atlantis® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the Atlantis® Conus Abutment to the endosseous implant.

The Atlantis® Crown is intended for use with an Atlantis® Abutment and an endosseous implant to function as a substructure that also serves as the final restoration in a partially or completely edentulous patient.

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.

A handwritten signature in blue ink, appearing to read 'Göran Forsmalm', written over a horizontal line.

Göran Forsmalm
Manager Regulatory Affairs
Platform Lead DIS



ANNEX

Item No.	Product Description
35020	Atlantis Abutment Screw
35020R	R Atlantis Abutment Screw
35040C	Atlantis Crown Cut-back
35040F	Atlantis Crown FullContour
35040LC	L Crown Cut-back
35040LF	L Atlantis Crown FullContour
35040RC	R Crown Cut-back
35040RF	R Atlantis Crown FullContour
35302	Atlantis Conus Abutm OD Ti
35302L	L Atlantis Conus Abutm OD Ti
35302R	R Atlantis Conus Abutm OD Ti
35302S	S Atlantis Conus Abutm OD Ti
35304	Atlantis Conus Abutm OD Ti Dup
35304L	L Atlantis Conus Abutm OD Ti Dup
35304R	R Atlantis Conus Abutm OD Ti Dup
35304S	S Atlantis Conus Abutm OD Ti Dup
35352	Atlantis Conus Abutm Custom Ti
35352L	L Atlantis Conus Abutm Custom Ti
35352R	R Atlantis Conus Abutm Custom Ti
35352S	S Atlantis Conus Abutm Custom Ti
35353	Atlantis Conus Abutm Cu Gold
35353L	L Atlantis Conus Abutm Cu Gold
35353R	R Atlantis Conus Abutm Cu Gold
35353S	S Atlantis Conus Abutm Cu Gold
35354	Atlantis Conus Abutm Cu Ti Dup
35354L	L Atlantis Conus Abutm Cu Ti Dup
35354R	R Atlantis Conus Abutm Cu Ti Dup
35354S	S Atlantis Conus Abutm Cu Ti Dup
35355	Atlantis Conus Abutm Cu Gold Dup
35355L	L Atlantis Conus Abutm Cu Gold Dup
35355R	R Atlantis Conus Abutm Cu Gold Dup
35355S	S Atlantis Conus Abutm Cu Gold Dup
35401	Atlantis Crown Abutm Zr 00
35401L	L Atlantis Crown Abutm Zr 00
35401R	R Atlantis Crown Abutm Zr 00
35401S	S Atlantis Crown Abutm Zr 00
35402	Atlantis Crown Abutment Ti



35402L	L Atlantis Crown Abutment Ti
35402R	R Atlantis Crown Abutment Ti
35402S	S Atlantis Crown Abutment Ti
35404	Atlantis Crown Abutm Ti Dup
35404L	L Atlantis Crown Abutm Ti Dup
35404R	R Atlantis Crown Abutm Ti Dup
35404S	S Atlantis Crown Abutm Ti Dup
35411	Atlantis Crown Abutm Zr 10
35411L	L Atlantis Crown Abutm Zr 10
35411R	R Atlantis Crown Abutm Zr 10
35411S	S Atlantis Crown Abutm Zr 10
35413	Atlantis Crown Abutm Zr 20
35413L	L Atlantis Crown Abutm Zr 20
35413R	R Atlantis Crown Abutm Zr 20
35413S	S Atlantis Crown Abutm Zr 20
35415	Atlantis Crown Abutm Zr 30
35415L	L Atlantis Crown Abutm Zr 30
35415R	R Atlantis Crown Abutm Zr 30
35415S	S Atlantis Crown Abutm Zr 30
35417	Atlantis Crown Abutm Zr 00T
35417L	L Atlantis Crown Abutm Zr 00T
35417R	R Atlantis Crown Abutm Zr 00T
35417S	S Atlantis Crown Abutm Zr 00T
35501	Atlantis Abutment Zr 00
35501L	L Atlantis Abutment Zr 00
35501R	R Atlantis Abutment Zr 00
35501S	S Atlantis Abutment Zr 00
35502	Atlantis Abutment Ti
35502L	L Atlantis Abutment Ti
35502R	R Atlantis Abutment Ti
35502S	S Atlantis Abutment Ti
35503	Atlantis Abutm Goldshaded Ti
35503L	L Atlantis Abutm Goldshaded Ti
35503R	R Atlantis Abutm Goldshaded Ti
35503S	S Atlantis Abutm Goldshaded Ti
35504	Atlantis Abutment Ti Duplicate
35504L	L Atlantis Abutment Ti Duplicate
35504R	R Atlantis Abutment Ti Duplicate
35504S	S Atlantis Abutment Ti Duplicate
35505	Atlantis Abutm Goldsh Ti Dup
35505L	L Atlantis Abutm Goldsh Ti Dup
35505R	R Atlantis Abutm Goldsh Ti Dup
35505S	S Atlantis Abutm Goldsh Ti Dup
35511	Atlantis Abutment Zr 10



35511L	L Atlantis Abutment Zr 10
35511R	R Atlantis Abutment Zr 10
35511S	S Atlantis Abutment Zr 10
35513	Atlantis Abutment Zr 20
35513L	L Atlantis Abutment Zr 20
35513R	R Atlantis Abutment Zr 20
35513S	S Atlantis Abutment Zr 20
35515	Atlantis Abutment Zr 30
35515L	L Atlantis Abutment Zr 30
35515R	R Atlantis Abutment Zr 30
35515S	S Atlantis Abutment Zr 30
35517	Atlantis Healing Abutment Ti
35517L	L Atlantis Healing Abutment Ti
35517R	R Atlantis Healing Abutment Ti
35517S	S Atlantis Healing Abutment Ti
35518	Atlantis Healing Abutment GS
35518L	L Atlantis Healing Abutment GS
35518R	R Atlantis Healing Abutment GS
35518S	S Atlantis Healing Abutment GS



REVISION HISTORY

Document Version	Change note / Description	PCO No
A	Supersedes DC-00054187:E New template. Compatibility chart has been updated with new interfaces for Crown on Ti abutment and Crown on Zr abutment.	
B	Compatibility chart has been updated with new interface for NobelActive WP 5.5	
C	Compatibility chart has been updated with new interface for MIS.	
D	New Atlantis Abutment has been included for healing purposes. Item No listed in Annex have been extended with suffix No's for each item No. Compatibility chart has been updated with new interfaces for Crown Abutments and Crown on Zr abutment	
E	Document content and enclosure unchanged, but scope updated to include all Angulated Screw Access options. The ASA option applies to the following products: <ul style="list-style-type: none"> • 35020 family – Atlantis Abutment Screw • 35040 family – Atlantis Crown • 35502 family – Atlantis Abutment Ti • 35503 family – Atlantis Abutment Gold-shaded Ti • 35504 family – Atlantis Abutment Ti Duplicate • 35505 family – Atlantis Abutment Gold-shaded Ti Duplicate The ASA option applies to these products when ordered for use with the following implant families: <ul style="list-style-type: none"> • Osseospeed EV & Osseospeed EV Profile • Osseospeed TX • Ankylos • Xive S/Frialit • Zimmer SV/TSV • Biohorizons Internal • MIS M4 & Seven • Straumann Bone Level • NobelActive & NobelReplace Conical Connection 	

Atlantis Compatibility Chart

Manufacturer	Connection	Implant selection list	Titanium/ Goldshaded Ti	Zirconia	Crown on Ti abutment	Crown on Zr abutment	ACA Ti	ACA Zr	Conus custom Ti	Conus overdenture Ti
BioHorizons	Internal									
BioHorizons	Internal	Internal 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BioHorizons	Internal	Internal 4.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BioHorizons	Internal	Internal 5.7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BioHorizons	External									
BioHorizons	External	External Implant 3.5	Yes	No	No	No	No	No	Yes	No
BioHorizons	External	External Implant 4.0	Yes	Yes	No	No	No	Yes	Yes	No
BioHorizons	External	External Implant 5.0	Yes	Yes	No	No	No	Yes	Yes	No
Biomet 3i	Internal									
Biomet 3i	Internal	Certain 3.25	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain 4.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain 5.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain 6.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain 4/3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain 5/4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 3/4/3 (3.4)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 4/5/4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 5/6/5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 4/3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 5/4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 6/5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain XP 4/5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	Internal	Certain XP 5/6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biomet 3i	External									
Biomet 3i	External	MicroMiniImplant 3.25	Yes	No	Yes	No	No	No	Yes	No
Biomet 3i	External	MiniImplant 3.25	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	Osseotite 3.75	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	Osseotite 4.0	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	Osseotite 5.0	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	Osseotite 6.0	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	OsseotiteXP 4/5	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Biomet 3i	External	OsseotiteXP 5/6	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Camlog	Internal									
Camlog	Internal	Camlog Screw Line Implant 3.3	Yes	No	Yes	No	Yes	No	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 3.8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 4.3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 5.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 6.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Camlog	Internal	Conelog Screw Line Implant 3.3	Yes	No	Yes	No	Yes	No	Yes	Yes
Camlog	Internal	Conelog Screw Line Implant 3.8	Yes	No	Yes	No	Yes	No	Yes	Yes
Camlog	Internal	Conelog Screw Line Implant 4.3	Yes	No	Yes	No	Yes	No	Yes	Yes
Camlog	Internal	Conelog Screw Line Implant 5.0	Yes	No	Yes	No	Yes	No	Yes	Yes

Atlantis Compatibility Chart

Manufacturer	Connection	Implant selection list	Titanium/ Goldshaded Ti	Zirconia	Crown on Ti abutment	Crown on Zr abutment	ACA Ti	ACA Zr	Conus custom Ti	Conus overdenture Ti
Keystone Dental	Internal									
	Internal	PrimeComx SD 3.3 / Genesis 3.8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	PrimeComx SD 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	PrimeComx RD 4.0 / Genesis 4.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	PrimeComx RD 4.1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	PrimeComx WD 5.0 / Genesis 5.5, 6.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	External									
	External	Restore SD 3.3	Yes	No	Yes	No	No	No	Yes	No
	External	Restore SD 3.4	Yes	No	Yes	No	No	No	Yes	No
	External	Restore RD 3.75	Yes	Yes	No	No	No	Yes	Yes	No
Keystone Dental	External	Restore RD 4.0	Yes	Yes	No	No	No	Yes	Yes	No
	External	Restore WD 5.0	Yes	No	Yes	No	No	No	Yes	No
	External	Restore WD 5.5	Yes	No	Yes	No	No	No	Yes	No
	External	Restore WD 6.0	Yes	No	Yes	No	No	No	Yes	No
	Internal									
	Internal	M4 NP 3.3	Yes	No	Yes	No	Yes	No	Yes	Yes
	Internal	M4 SP 3.7, 4.2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	M4 WP 5.0, 6.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	SEVEN NP 3.3	Yes	No	Yes	No	Yes	No	Yes	Yes
	Internal	SEVEN SP 3.75, 4.2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nobel Biocare	Internal									
	Internal	NobelActive 3.0	Yes	No	Yes	No	Yes	No	No	No
	Internal	NobelActive NP 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelActive RP 4.3, 5.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelActive WP 5.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace NP 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace RP 4.3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace WP 5.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace HL 3.8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace HL 4.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace Conical Connection NP 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Internal	NobelReplace Conical Connection RP 4.3, 5.0	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	External									
	External	Brånemark System NP 3.3	Yes	No	Yes	No	Yes	No	Yes	Yes
	External	Brånemark System RP 3.75	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
	External	Brånemark System RP 4.0	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
	External	Brånemark System WP 5.0	Yes	Yes	Yes	No	Yes	Yes	Yes	No
	External	Brånemark System WP 5.5	Yes	Yes	Yes	No	Yes	Yes	Yes	No
	External	SterOss Replica 3.1	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss Replica 3.5	Yes	No	Yes	No	No	No	Yes	No
Nobel Biocare	External	SterOss Replica 4.3	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss Replica 5.0	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss Replica 6.0	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss HL 3.25	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss HL 3.8	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss HL 4.5	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss HL 5.0	Yes	No	Yes	No	No	No	Yes	No
	External	SterOss HL 6.0	Yes	No	Yes	No	No	No	Yes	No
	Internal									
	Internal	Osstem TS Mini 3.5	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

Atlantis Compatibility Chart

Manufacturer	Connection	Implant selection list	Titanium/ Goldshaded TI	Zirconia	Crown on TI abutment	Crown on Zr abutment	ACA TI	ACA Zr	Conus custom TI	Conus overdenture TI
Osstem	Internal	Osstem TS Regular 4.0, 4.5, 5.0, 6.0, 7.0	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Straumann	Internal									
Straumann	Internal	Bone Level 3.3 NC (Narrow CrossFit)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Straumann	Internal	Bone Level 4.1 RC (Regular CrossFit)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Straumann	Internal	Bone Level 4.8 RC (Regular CrossFit)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Straumann	Internal	Standard/Standard Plus 4.8 RN (Regular Neck)	Yes	No	Yes	No	Yes	No	Yes	Yes
Straumann	Internal	Standard/Standard Plus 4.8 WN (Wide Neck)	Yes	No	Yes	No	Yes	No	Yes	Yes
Straumann	External									
Straumann	External	Standard Plus 3.3 NN (Narrow Neck)	Yes	No	No	No	No	No	Yes	No
Zimmer Dental	Internal									
Zimmer Dental	Internal	Tapered Screw-Vent 3.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 4.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 5.7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 3.5 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 4.5 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 5.7 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 4.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.3 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.7 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 4.5 friction fit	Yes	No	Yes	No	Yes	No	Yes	Yes
Zimmer Dental	Internal	SwissPlus 4.8	Yes	No	Yes	No	Yes	No	Yes	Yes