



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® Temporary Crown
(as listed in Annex)

The Atlantis® Temporary Crown is intended for use with an Atlantis® Abutment and an endosseous implant as a functional restoration, up to 12 months, until a permanent crown is constructed.

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, reading 'Göran Forsmalm', written over a horizontal line.

Göran Forsmalm
Manager Regulatory Affairs
Platform Lead DIS

ANNEX

Item No.	Product Description
35011F	Atlantis Temporary Crown
35011LF	L Atlantis Temporary Crown
35011RF	R Atlantis Temporary Crown

REVISION HISTORY

Document Version	Change note / Description	PCO No
A	First issue	-
B	Including Atlantis Temporary crown with screw access hole. Compatibility chart has been updated with new interfaces for Cement and Screw retained Temporary crown	-

Atlantis Compatibility Chart for Temporary Crown

Manufacturer	Connection	Implant selection list	Cement retained		Screw retained
			Temporary Crown on Ti and Gold shaded abutment	Temporary Crown on Zr abutment	Temporary Crown on Ti and Gold shaded abutment
BioHorizons	Internal				
BioHorizons	Internal	Internal 3.5	Yes	Yes	Yes
BioHorizons	Internal	Internal 4.5	Yes	Yes	Yes
BioHorizons	Internal	Internal 5.7	Yes	Yes	Yes
BioHorizons	External				
BioHorizons	External	External Implant 3.5	Yes	No	Yes
BioHorizons	External	External Implant 4.0	Yes	Yes	Yes
BioHorizons	External	External Implant 5.0	Yes	Yes	Yes
Biomet 3i	Internal				
Biomet 3i	Internal	Certain 3.25	Yes	Yes	Yes
Biomet 3i	Internal	Certain 4.0	Yes	Yes	Yes
Biomet 3i	Internal	Certain 5.0	Yes	Yes	Yes
Biomet 3i	Internal	Certain 6.0	Yes	Yes	Yes
Biomet 3i	Internal	Certain 4/3	Yes	Yes	Yes
Biomet 3i	Internal	Certain 5/4	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 3/4/3 (3.4)	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 4/5/4	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 5/6/5	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 4/3	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 5/4	Yes	Yes	Yes
Biomet 3i	Internal	Certain Prevail 6/5	Yes	Yes	Yes
Biomet 3i	Internal	Certain XP 4/5	Yes	Yes	Yes
Biomet 3i	Internal	Certain XP 5/6	Yes	Yes	Yes
Biomet 3i	External				
Biomet 3i	External	MicroMiniplant 3.25	Yes	No	Yes
Biomet 3i	External	Miniplant 3.25	Yes	Yes	Yes
Biomet 3i	External	Osseotite 3.75	Yes	Yes	Yes
Biomet 3i	External	Osseotite 4.0	Yes	Yes	Yes
Biomet 3i	External	Osseotite 5.0	Yes	Yes	Yes
Biomet 3i	External	Osseotite 6.0	Yes	Yes	Yes
Biomet 3i	External	OsseotiteXP 4/5	Yes	Yes	Yes
Biomet 3i	External	OsseotiteXP 5/6	Yes	Yes	Yes
Camlog	Internal				
Camlog	Internal	Camlog Screw Line Implant 3.3	Yes	No	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 3.8	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 4.3	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 5.0	Yes	Yes	Yes
Camlog	Internal	Camlog Screw Line / Root-line Implant 6.0	Yes	Yes	Yes
Camlog	Internal	Conelog Screw Line Implant 3.3	Yes	No	Yes
Camlog	Internal	Conelog Screw Line Implant 3.8	Yes	No	Yes
Camlog	Internal	Conelog Screw Line Implant 4.3	Yes	No	Yes
Camlog	Internal	Conelog Screw Line Implant 5.0	Yes	No	Yes

Attachment to DEC-00067267 Version: B

Atlantis Compatibility Chart for Temporary Crown

Manufacturer	Connection	Implant selection list	Temporary Crown on Ti and Gold shaded abutment	Temporary Crown on Zr abutment	Temporary Crown on Ti and Gold shaded abutment
Dentsply Implants	Internal				
Dentsply Implants	Internal	ANKYLOS C/X 3.5, 4.5, 5.5, 7.0 /X (indexed)	Yes	Yes	Yes
Dentsply Implants	Internal	ANKYLOS C/X 3.5, 4.5, 5.5, 7.0 C/ (non-indexed)	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed TX 3.0 - Yellow	Yes	No	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed TX 3.5, 4.0 - Aqua	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed TX 4.5, 5.0 - Lilac	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed 3.0 - Yellow	Yes	No	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed 3.5, 4.0 - Aqua	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed 4.5, 5.0 - Lilac	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed 4.0 Blue (Previous)	Yes	No	No
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed TX Profile 4.5, 5.0	Yes	No	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed EV 3.0 - Green	Yes	No	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed EV 3.6 - Purple	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed EV 4.2 - Yellow	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed EV 4.8 - Blue	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed EV 5.4 - Brown	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed Profile EV 4.2 - Yellow	Yes	Yes	Yes
Dentsply Implants	Internal	ASTRA TECH Implant System OsseoSpeed Profile EV 4.8 - Blue	Yes	Yes	Yes
Dentsply Implants	Internal	XIVE S 3.0	Yes	No	Yes
Dentsply Implants	Internal	XIVE S 3.4	Yes	Yes	Yes
Dentsply Implants	Internal	XIVE S 3.8	Yes	Yes	Yes
Dentsply Implants	Internal	XIVE S 4.5	Yes	Yes	Yes
Dentsply Implants	Internal	XIVE S 5.5	Yes	Yes	Yes
Dentsply Implants	Internal	Frialit 3.4	Yes	Yes	Yes
Dentsply Implants	Internal	Frialit 3.8	Yes	Yes	Yes
Dentsply Implants	Internal	Frialit 4.5	Yes	Yes	Yes
Dentsply Implants	Internal	Frialit 5.5	Yes	Yes	Yes

Atlantis Compatibility Chart for Temporary Crown

Manufacturer	Connection	Implant selection list	Temporary Crown on Ti and Gold shaded abutment	Temporary Crown on Zr abutment	Temporary Crown on Ti and Gold shaded abutment
Keystone Dental	Internal				
Keystone Dental	Internal	PrimaConnex SD 3.3 / Genesis 3.8	Yes	Yes	Yes
Keystone Dental	Internal	PrimaConnex SD 3.5	Yes	Yes	Yes
Keystone Dental	Internal	PrimaConnex RD 4.0 / Genesis 4.5	Yes	Yes	Yes
Keystone Dental	Internal	PrimaConnex RD 4.1	Yes	Yes	Yes
Keystone Dental	Internal	PrimaConnex WD 5.0 / Genesis 5.5, 6.5	Yes	Yes	Yes
Keystone Dental	External				
Keystone Dental	External	Restore SD 3.3	Yes	No	Yes
Keystone Dental	External	Restore SD 3.4	Yes	No	Yes
Keystone Dental	External	Restore RD 3.75	Yes	Yes	Yes
Keystone Dental	External	Restore RD 4.0	Yes	Yes	Yes
Keystone Dental	External	Restore WD 5.0	Yes	No	Yes
Keystone Dental	External	Restore WD 5.5	Yes	No	Yes
Keystone Dental	External	Restore WD 6.0	Yes	No	Yes
MIS	Internal				
MIS	Internal	M4 NP 3.3	Yes	No	Yes
MIS	Internal	M4 SP 3.7, 4.2	Yes	Yes	Yes
MIS	Internal	M4 WP 5.0, 6.0	Yes	Yes	Yes
MIS	Internal	SEVEN NP 3.3	Yes	No	Yes
MIS	Internal	SEVEN SP 3.75, 4.2	Yes	Yes	Yes
MIS	Internal	SEVEN WP 5.0, 6.0	Yes	Yes	Yes
Nobel Biocare	Internal				
Nobel Biocare	Internal	NobelActive 3.0	Yes	No	Yes
Nobel Biocare	Internal	NobelActive NP 3.5	Yes	Yes	Yes
Nobel Biocare	Internal	NobelActive RP 4.3, 5.0	Yes	Yes	Yes
Nobel Biocare	Internal	NobelActive WP 5.5	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace NP 3.5	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace RP 4.3	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace WP 5.0	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace 6.0	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace Conical Connection NP 3.5	Yes	Yes	Yes
Nobel Biocare	Internal	NobelReplace Conical Connection RP 4.3, 5.0	Yes	Yes	Yes
Nobel Biocare	External				
Nobel Biocare	External	Brånemark System NP 3.3	Yes	No	Yes
Nobel Biocare	External	Brånemark System RP 3.75	Yes	Yes	Yes
Nobel Biocare	External	Brånemark System RP 4.0	Yes	Yes	Yes
Nobel Biocare	External	Brånemark System WP 5.0	Yes	Yes	Yes
Nobel Biocare	External	Brånemark System WP 5.5	Yes	Yes	Yes
Nobel Biocare	External	SteriOss Replace 3.1	Yes	No	Yes
Nobel Biocare	External	SteriOss Replace 3.5	Yes	No	Yes
Nobel Biocare	External	SteriOss Replace 4.3	Yes	No	Yes
Nobel Biocare	External	SteriOss Replace 5.0	Yes	No	Yes
Nobel Biocare	External	SteriOss Replace 6.0	Yes	No	Yes
Nobel Biocare	External	SteriOss HL 3.25	Yes	No	Yes
Nobel Biocare	External	SteriOss HL 3.8	Yes	No	Yes
Nobel Biocare	External	SteriOss HL 4.5	Yes	No	Yes
Nobel Biocare	External	SteriOss HL 5.0	Yes	No	Yes
Nobel Biocare	External	SteriOss HL 6.0	Yes	No	Yes
Osstem	Internal				
Osstem	Internal	Osstem TS Mini 3.5	Yes	Yes	Yes
Osstem	Internal	Osstem TS Regular 4.0, 4.5, 5.0, 6.0, 7.0	Yes	Yes	Yes
Straumann	Internal				
Straumann	Internal	Bone Level 3.3 NC (Narrow CrossFit)	Yes	Yes	Yes
Straumann	Internal	Bone Level 4.1 RC (Regular CrossFit)	Yes	Yes	Yes
Straumann	Internal	Bone Level 4.8 RC (Regular CrossFit)	Yes	Yes	Yes
Straumann	Internal	Standard/Standard Plus 4.8 RN (Regular Neck)	Yes	No	Yes
Straumann	Internal	Standard/Standard Plus 4.8 WN (Wide Neck)	Yes	No	Yes
Straumann	External				

Attachment to DEC-00067267 Version: B

Atlantis Compatibility Chart for Temporary Crown

Manufacturer	Connection	Implant selection list	Temporary Crown on Ti and Gold shaded abutment	Temporary Crown on Zr abutment	Temporary Crown on Ti and Gold shaded abutment
Straumann	External	Standard Plus 3.3 NN (Narrow Neck)	Yes	No	Yes
Zimmer Dental	Internal				
Zimmer Dental	Internal	Tapered Screw-Vent 3.5	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 4.5	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 5.7	Yes	Yes	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 3.5 friction fit	Yes	No	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 4.5 friction fit	Yes	No	Yes
Zimmer Dental	Internal	Tapered Screw-Vent 5.7 friction fit	Yes	No	Yes
Zimmer Dental	Internal	Screw-Vent 3.3	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.7	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 4.5	Yes	Yes	Yes
Zimmer Dental	Internal	Screw-Vent 3.3 friction fit	Yes	No	Yes
Zimmer Dental	Internal	Screw-Vent 3.7 friction fit	Yes	No	Yes
Zimmer Dental	Internal	Screw-Vent 4.5 friction fit	Yes	No	Yes
Zimmer Dental	Internal	SwissPlus 4.8	Yes	No	Yes