Dentsply Sirona Implants

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
Research Campus 10
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PRODUCT NAME

Simplant® Guide
(as listed in Annex)

The Simplant® Guide is intended for use in assisting placement of dental implants.

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

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ANNEX

Item No.	Product Description
37501	Simplant Guide - 1 implants
37502	Simplant Guide - 2 implants
37503	Simplant Guide - 3 implants
37504	Simplant Guide - 4 implants
37505	Simplant Guide - 5 implants
37506	Simplant Guide - 6 implants
37507	Simplant Guide - 7 implants
37508	Simplant Guide - 8 implants
37509	Simplant Guide - 9 implants
37510	Simplant Guide - 10 implants
37511	Simplant Guide – 11 implants
37512	Simplant Guide – 12 implants
37513	Simplant Guide - 13 implants
37514	Simplant Guide – 14 implants
37515	Simplant Guide - 15 implants
37516	Simplant Guide - 16 implants
54500220	Simplant Guide – duplicate guide
54500226	Simplant Guide – reduction guide

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Revision History

Document Version	Change note / Description	PCO No
00	First issue	-
01	Change of raw material (resin)	-
02	Change of shelf life (Document version 02 was later uploaded in PDMLink as version A)	
B	Replaces version 02 Change packaging for Simplant Guide Remove item 54500228 (Movex status 90)	RPT-00072304