

Document type
DOCDocument no.
131506Part
000Version
26

DECLARATION OF CONFORMITY

Name of Product Family: *Instruments, Class IIa, Rule 6*

I, the undersigned, hereby declare that the medical devices specified in the product list below conform to the relevant requirements of EC Directive 93/42/EEC and have been CE marked in accordance with Annex II as a Class IIa device.

This declaration is supported by the Annex II (excluding Section 4) EC Certificate number CE 00353 issued by BSI (Notified Body No. 2797. Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands) and Certificate of Registration number MD 81731 for operation of a quality management system which complies with the requirements of ISO 13485:2016.

DocuSigned by:

739FFA96E212466...

Susanna Jinks
Global Director Regulatory Affairs

24-Jan-2022 | 23:58 PST

Issue Date

Manufacturer¹ (exclusively responsible for this Declaration of Conformity):

Nobel Biocare AB
PO Box 5190, 402 26
Västra Hamngatan 1, 411 17
Göteborg, Sweden

¹ See table below for information under which legal manufacturer the individual articles have been manufactured

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**



Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
DIA 187-0	Machine screwdriver Hex Long	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
DIA 188-0	Machine screwdriver Slot Short	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
DIA 189-0	Machine screwdriver Slot Long	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
DIA 578-0	Brånemark System® Zygoma Round Bur	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
2430	Screwdriver Machine Slot	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
28910	Tissue Punch 3.0	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
28977	Bone Mill Brånemark System® NP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
28978	Bone Mill Brånemark System® RP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
28979	Bone Mill Brånemark System® WP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
28980	Cover Screw Mill Brånemark System® NP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
28981	Cover Screw Mill Brånemark System® RP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
28982	Cover Screw Mill Brånemark System® WP	Ila	Rule 6	2002-10-11	2797	Nobel Biocare AB
29027	Screwdriver Machine Ball Abutment 24 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29081	Connection to Handpiece	Ila	Rule 6	2002-10-18	2797	Nobel Biocare AB
29126	Implant Driver Brånemark System® NP 26 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29127	Implant Driver Brånemark System® NP 34 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29129	Implant Driver Brånemark System® RP 21 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29130	Implant Driver Brånemark System® RP 26 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29131	Implant Driver Brånemark System® RP 34 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29134	Implant Driver Brånemark System® WP 21 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29135	Implant Driver Brånemark System® WP 26 mm	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29151	Screwdriver Machine UniGrip™ 20 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29152	Screwdriver Machine UniGrip™ 25 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29153	Screwdriver Machine UniGrip™ 30 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29154	Screwdriver Machine UniGrip™ 35 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29158	Screwdriver Machine Multi-unit 21 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29159	Screwdriver Machine Multi-unit Brånemark System® WP 20 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29164	Drill Extension Shaft	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29367	Drill Tapered 3.5x10 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29368	Drill Tapered 3.5x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29369	Drill Tapered 3.5x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26



Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
29370	Drill Tapered 4.3x10 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29371	Drill Tapered 4.3x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29372	Drill Tapered 4.3x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29373	Drill Tapered 5x10 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29374	Drill Tapered 5x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29375	Drill Tapered 5x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29377	Dense Bone Drill Tapered 3.5x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29378	Dense Bone Drill Tapered 3.5x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29380	Dense Bone Drill Tapered 4.3x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29381	Dense Bone Drill Tapered 4.3x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29383	Dense Bone Drill Tapered 5x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29384	Dense Bone Drill Tapered 5x16 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29508	Implant Driver NobRpl RP Short	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29509	Implant Driver NobRpl RP Long	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29510	Implant Driver NobRpl WP Short	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29511	Implant Driver NobRpl WP Long	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
29628	Tissue Punch NP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29629	Tissue Punch RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29630	Tissue Punch WP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29967	Drill Tapered 6x10 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29968	Drill Tapered 6x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29970	Dense Bone Drill Tapered 6x13 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
29997	Implant Driver NobRpl 6.0 Short	Ila	Rule 6	2002-10-09	2797	Nobel Biocare AB
31278	Twist Drill 1.5x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
31604	Implant Driver NobRpl NP Short	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
31625	Implant Driver NobRpl NP Long	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32075	Drill Tapered NP 3.5x8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32076	Drill Tapered RP 4.3x8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32077	Drill Tapered WP 5x8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32078	Drill Tapered 6.0 6x8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32089	Screw Tap Tapered NP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32090	Screw Tap Tapered RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
32091	Screw Tap Tapered WP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32092	Screw Tap Tapered 6.0	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32249	Drill Tapered 6.0 6x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32250	Dense Bone Drill Tapered 6.0 6x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32260	Twist Step Drill 2.4/2.8 7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32261	Twist Step Drill 2.4/2.8 7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32262	Twist Step Drill 2.4/2.8 10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32263	Twist Step Drill 3.2/3.6 7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32264	Twist Step Drill 3.2/3.6 7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32265	Twist Step Drill 3.2/3.6 10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32266	Twist Drill 3x7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32267	Twist Drill 3x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32268	Twist Drill 3x10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32269	Twist Drill 3.2x7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32270	Twist Drill 3.2x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32271	Twist Drill 3.2x10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32272	Twist Drill 3.4x7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32273	Twist Drill 3.4x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32274	Twist Drill 3.4x10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32275	Twist Step Drill 3.8/4.2 7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32276	Twist Step Drill 3.8/4.2 7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32277	Twist Step Drill 3.8/4.2 10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32278	Twist Drill 5x7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32279	Twist Drill 5x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32280	Twist Drill 5x10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32281	Brånemark System® Counterbore NP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32283	Brånemark System® Counterbore RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32285	Brånemark System® Counterbore WP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32290	Screw Tap RP Ø3.75 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32291	Screw Tap RP Ø3.75 7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32292	Screw Tap WP Ø5 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32293	Screw Tap WP Ø5 7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
32294	Screw Tap NobRpl 6.0/Bmk WP Ø6 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32295	Screw Tap NobRpl 6.0/Bmk WP Ø6 7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32296	Twist Drill w Tip 2x7-10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32297	Twist Drill w Tip 2x7-15mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32299	Twist Drill w Tip 2x10-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32413	Implant Driver NobRpl 6.0 Long	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32628	Brånemark System® Zygoma Twist Drill 2.9 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32629	Brånemark System® Zygoma Twist Drill 2.9 mm short	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32630	Brånemark System® Zygoma Pilot Drill 3.5 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32631	Brånemark System® Zygoma Twist Drill 3.5 mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32632	Brånemark System® Zygoma Twist Drill 3.5 mm short	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32672	Tissue Punch 6.0	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32736	Guided Start Drill/Counterbore Bmk Syst NP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32737	Guided Start Drill/Counterbore NobRpl NP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32738	Guided Start Drill/Counterb Bmk Syst RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32739	Guided Start Drill/Counterbore NobRpl RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32740	Guided Start Drill/Counterbore Bmk Syst WP Ø5	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32741	Guided Start Drill/Counterbore NobRpl WP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32742	Guided Start Drill/Counterbore Bmk Syst WP Ø6	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32743	Guided Start Drill/Counterbore NobRpl 6.0	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32746	Guided Twist Drill 2x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32747	Guided Twist Drill 2.8x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32748	Guided Twist Drill 3x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32749	Guided Twist Drill 3.2x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32750	Guided Twist Drill 3.4x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32751	Guided Twist Drill 3.8x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32752	Guided Twist Drill 4.2x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32753	Guided Twist Drill 5x(10+)7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32791	Brånemark System® Zygoma Pilot Drill 3.5 mm short	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32827	Guided Drill Tapered NP 3.5x(+)8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32828	Guided Drill Tapered NP 3.5x(+)10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32829	Guided Drill Tapered NP 3.5x(+)13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26



Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
32830	Guided Drill Tapered NP 3.5x(+) 16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32831	Guided Drill Tapered RP 4.3x(+) 8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32832	Guided Drill Tapered RP 4.3x(+) 10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32833	Guided Drill Tapered RP 4.3x(+) 13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32834	Guided Drill Tapered RP 4.3x(+) 16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32835	Guided Drill Tapered WP 5x(+) 8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32836	Guided Drill Tapered WP 5x(+) 10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32837	Guided Drill Tapered WP 5x(+) 13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32838	Guided Drill Tapered WP 5x(+) 16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32839	Guided Drill Tapered 6.0 6x(+) 8mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32840	Guided Drill Tapered 6.0 6x(+) 10mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32841	Guided Drill Tapered 6.0 6x(+) 13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32842	Guided Drill Tapered 6.0 6x(+) 16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32844	Guided Dense Bone Drill Tapered NP 3.5x13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32845	Guided Dense Bone Drill Tapered NP 3.5x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32847	Guided Dense Bone Drill Tapered RP 4.3x13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32848	Guided Dense Bone Drill Tapered RP 4.3x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32850	Guided Dense Bone Drill Tapered WP 5x13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32851	Guided Dense Bone Drill Tapered WP 5x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32853	Guided Dense Bone Drill Tapered 6.0 6x13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32854	Guided Dense Bone Drill Tapered 6.0 6x16mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32855	Guided Screw Tap NP 10-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32857	Guided Screw Tap RP Ø3.75 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32858	Guided Screw Tap Tapered RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32859	Guided Screw Tap WP Ø5 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32860	Guided Screw Tap Tapered WP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32861	Guided Screw Tap 6.0/WP Ø6 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32862	Guided Screw Tap Tapered 6.0	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
32863	Guided Implant Mount Bmk Syst NP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
32864	Guided Implant Mount NobRpI NP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
32865	Guided Implant Mount Bmk Syst RP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
32866	Guided Implant Mount NobRpI RP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
32868	Guided Implant Mount Bmk Syst WP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
32869	Guided Implant Mount NobRpl WP	Ila	Rule 6	2005-05-25	2797	Nobel Biocare AB
32871	Guided Implant Mount NobRpl 6.0	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
33063	Drill Stop Ø2	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33064	Drill Stop Ø2.8	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33065	NOBELREPLACE® Connection to handpiece	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33066	Guided Twist Drill Ø1.5mmx20mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33072	Screw Tap RP Ø4 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33073	Screw Tap RP Ø4 7-18mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33075	Drill Stop Ø3	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33077	Drill Stop Ø3.2	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33078	Drill Stop Ø3.4	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33080	Drill Stop Ø3.8	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33081	Drill Stop Ø4.2	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33084	Drill Stop Ø3.6	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33107	Guided Twist Drill 2x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33108	Guided Twist Drill 2.8x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33109	Guided Twist Drill 3x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33113	Guided StartDrill/Counterbore former MkIII RP	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33114	Guided Screw Tap RP Ø4 7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33115	Guided Twist Drill 3.2x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33117	Guided Twist Drill 3.4x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33118	Guided Twist Drill 3.8x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33119	Guided Twist Drill 4.2x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33120	Guided Twist Drill 5x(10+)7-13mm	Ila	Rule 6	2007-03-13	2797	Nobel Biocare AB
33392	Bone Mill with Guide Brånemark System® NP Ø4.5	Ila	Rule 6	2007-02-13	2797	Nobel Biocare AB
33393	Bone Mill with Guide Brånemark System® RP Ø5.1	Ila	Rule 6	2007-02-13	2797	Nobel Biocare AB
33495	Bone Mill with Guide Brånemark System® WP Ø6.5	Ila	Rule 6	2007-02-13	2797	Nobel Biocare AB
33505	Bone Mill with Guide NOBELREPLACE® 6.0 Ø7	Ila	Rule 6	2007-02-13	2797	Nobel Biocare AB
34582	Twist Step Drill 4.2/4.6 7-15mm	Ila	Rule 6	2007-08-24	2797	Nobel Biocare AB
34583	Twist Step Drill 4.2/4.6 10-18mm	Ila	Rule 6	2007-08-24	2797	Nobel Biocare AB
34638	Twist Step Drill 2.8/3.2 7-15mm	Ila	Rule 6	2007-08-24	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
34639	Twist Step Drill 2.8/3.2 10-18mm	Ila	Rule 6	2007-08-24	2797	Nobel Biocare AB
34995	Implant Driver NobelActive Internal NP 28mm	Ila	Rule 6	2009-02-04	2797	Nobel Biocare AB
34996	Implant Driver NobelActive Internal NP 36mm	Ila	Rule 6	2009-02-04	2797	Nobel Biocare AB
34997	Implant Driver NobelActive Internal RP 28mm	Ila	Rule 6	2009-02-04	2797	Nobel Biocare AB
34998	Implant Driver NobelActive Internal RP 36mm	Ila	Rule 6	2009-02-04	2797	Nobel Biocare AB
35426	Guide Drill	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35839	Guided Twist Step Drill Ø2.4/2.8 (10+) 7-13mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35840	Guided Twist Step Drill Ø2.8/3.2 (10+) 7-13mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35841	Guided Twist Step Drill Ø3.2/3.6 (10+) 7-13mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35842	Guided Twist Step Drill Ø3.8/4.2 (10+) 7-13mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35843	Guided Twist Step Drill Ø4.2/4.6 (10+) 7-13mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
35844	Guided Twist Step Drill Ø2.4/2.8 (10+) 7-18mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
35875	Guided Twist Step Drill Ø2.8/3.2 (10+) 7-18mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
35876	Guided Twist Step Drill Ø3.2/3.6 (10+) 7-18mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
35877	Guided Twist Step Drill Ø3.8/4.2 (10+) 7-18mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
35878	Guided Screw Tap NobelActive NP 8.5-10mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35879	Guided Screw Tap NobelActive RP 4.3x8.5-10mm	Ila	Rule 6	2009-07-08	2797	Nobel Biocare AB
35880	Guided Screw Tap NobelActive RP 5.0x8.5-10mm	Ila	Rule 6	2009-09-22	2797	Nobel Biocare AB
36113	Drill Tapered NP 3.5x11.5 mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36114	Drill Tapered RP 4.3x11.5 mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36115	Drill Tapered WP 5.0x11.5 mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36116	Drill Tapered 6.0 6x11.5 mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36117	Drill Tapered 2 mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36118	Precision Drill	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36119	Guided Drill Tapered NP 3.5x(+)11.5mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36120	Guided Drill Tapered RP 4.3x(+)11.5mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36121	Guided Drill Tapered WP 5x(+)11.5mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36122	Guided Drill Tapered 6.0 6x(+)11.5mm	Ila	Rule 6	2010-08-25	2797	Nobel Biocare AB
36123	Guided Twist Drill Tapered 2x(10+)8-16mm	Ila	Rule 6	2011-05-04	2797	Nobel Biocare AB
36124	Implant Driver NobelReplace™ NP Short	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36125	Implant Driver NobelReplace™ NP Long	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36126	Implant Driver NobelReplace™ RP Short	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
36127	Implant Driver NobelReplace™ RP Long	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36128	Implant Driver NobelReplace™ WP Short	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36129	Implant Driver NobelReplace™ WP Long	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36130	Implant Driver NobelReplace™ 6.0 Short	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36131	Implant Driver NobelReplace™ 6.0 Long	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36717	Screw Tap Tapered NP	Ila	Rule 6	2011-07-13	2797	Nobel Biocare AB
36718	Implant Driver Conical Connection NP 28mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36719	Implant Driver Conical Connection NP 37mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36720	Implant Driver Conical Connection RP 28mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36721	Implant Driver Conical Connection RP 37mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36773	Implant Driver Conical Connection 3.0 28mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36774	Implant Driver Conical Connection 3.0 37mm	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36830	Bone Mill with Guide NobelReplace™ NP Ø4.6	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36831	Bone Mill with Guide NobelReplace™ RP Ø5.3	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
36832	Bone Mill with Guide NobelReplace™ WP Ø6.5	Ila	Rule 6	2011-08-22	2797	Nobel Biocare AB
37045	Drill Tapered NP 3.5x8 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37048	Dense Bone Drill Tapered 6.0 6x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37049	Dense Bone Drill Tapered 6.0 6x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37050	Screw Tap Tapered NP Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37051	Screw Tap Tapered RP Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37052	Screw Tap Tapered WP Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37053	Screw Tap Tapered 6.0 Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37075	Drill Tapered NP 3.5x10 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37076	Drill Tapered NP 3.5x11.5 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37077	Drill Tapered NP 3.5x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37078	Drill Tapered NP 3.5x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37079	Drill Tapered RP 4.3x8 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37080	Drill Tapered RP 4.3x10 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37081	Drill Tapered RP 4.3x11.5 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37082	Drill Tapered RP 4.3x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37083	Drill Tapered RP 4.3x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37084	Drill Tapered WP 5x8 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26



Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
37085	Drill Tapered WP 5x10 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37086	Drill Tapered WP 5x11.5 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37087	Drill Tapered WP 5x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37088	Drill Tapered WP 5x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37089	Drill Tapered 6.0 6x8 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37090	Drill Tapered 6.0 6x10 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37091	Drill Tapered 6.0 6x11.5 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37092	Drill Tapered 6.0 6x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37093	Drill Tapered 6.0 6x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37094	Dense Bone Drill Tapered NP 3.5x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37095	Dense Bone Drill Tapered NP 3.5x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37096	Dense Bone Drill Tapered RP 4.3x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37097	Dense Bone Drill Tapered RP 4.3x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37098	Dense Bone Drill Tapered WP 5x13 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37099	Dense Bone Drill Tapered WP 5x16 mm Single-Patient Use	Ila	Rule 6	2012-02-10	2797	Nobel Biocare AB
37149	Guided Implant Mount NobRpl CC NP 3.5	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37150	Guided Implant Mount NobRpl CC RP 4.3	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37151	Guided Implant Mount NobRpl CC RP 5.0	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37152	Guided Start Drill	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37153	Guided Tissue Punch for NP-sleeve	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37154	Guided Tissue Punch for RP-sleeve	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37155	Guided Tissue Punch for WP/6.0-sleeve (5.0mm implants)	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37156	Guided Tissue Punch for WP/6.0-sleeve (6.0mm implants)	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37167	Guided Counterbore NobelReplace® 3.5	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37168	Guided Counterbore NobelReplace® 4.3	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37169	Guided Counterbore NobelReplace® 5.0	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37170	Guided Counterbore NobelReplace® 6.0	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37171	Guided Screw Tap Tapered NP	Ila	Rule 6	2012-07-03	2797	Nobel Biocare AB
37331	Twist Drill 3.8 x 7-10mm	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB
37332	Twist Drill 3.8 x 7-15mm	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB
37335	Pilot Drill 2.0/2.8mm	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB
37338	Brånemark System Counterbore Mk III NP	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
37339	Brånemark System Counterbore Mk III RP	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB
37341	Brånemark System Counterbore Mk III RP, long shaft	Ila	Rule 6	2013-02-04	2797	Nobel Biocare AB
37379	Omnigrip™ Screwdriver Machine 20mm	Ila	Rule 6	2013-12-05	2797	Nobel Biocare AB
37380	Omnigrip™ Screwdriver Machine 25mm	Ila	Rule 6	2013-12-05	2797	Nobel Biocare AB
37381	Omnigrip™ Screwdriver Machine 30mm	Ila	Rule 6	2013-12-05	2797	Nobel Biocare AB
37382	Omnigrip™ Screwdriver Machine 35mm	Ila	Rule 6	2013-12-05	2797	Nobel Biocare AB
37397	Guided Pilot Twist Drill 1.5x(10+)10-15mm	Ila	Rule 6	2013-08-30	2797	Nobel Biocare AB
37471	Impl Retrieval Instrument Ext Hex & Tri-Channel NP/RP 22mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37472	Impl Retrieval Instrument Ext Hex & Tri-Channel NP/RP 31mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37473	Implant Retrieval Instrument CC 3.0 31mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37474	Implant Retrieval Instrument CC NP & Ext Hex WP 22mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37475	Implant Retrieval Instrument CC RP & Tri-Channel WP 22mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37476	Implant Retrieval Instrument Tri-Channel 6.0 22mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37477	Trephine Drill 3.2/4.0mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37497	Screw Tap Repair M1.4	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37498	Screw Tap Repair M1.6	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37499	Screw Tap Repair M1.8	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37500	Screw Tap Repair M2.5	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37501	Abutment Screw Retrieval Reverse Drill 3.0/NP	Ila	Rule 6	2015-07-20	2797	Nobel Biocare AB
37502	Abutment Screw Retrieval Reverse Drill RP/WP/6.0	Ila	Rule 6	2015-07-20	2797	Nobel Biocare AB
37503	Abutment Screw Retrieval Instrument 3.0/NP	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37504	Abutment Screw Retrieval Instrument RP/WP/6.0	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37505	Abutment Screw Remover 3.0	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37506	Abutment Screw Remover NP	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37507	Abutment Screw Remover RP/WP/6.0	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37517	Screw Tap Repair M2.0	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37614	Twist Drill with Tip 2.0x18-25mm	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37616	Twist Drill 3.2x18-25mm	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37617	Twist Drill 3.4x18-25mm	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37618	Twist Step Drill 2.4/2.8x18-25mm	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37619	Twist Drill w Tip 2x18-25mm, long shaft	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37620	Twist Step Drill 2.4/2.8x18-25mm, long shaft	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type
DOC

Document no.
131506

Part
000

Version
26

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
37627	Screw Tap Ø3.3 7-15mm	Ila	Rule 6	2016-02-09	2797	Nobel Biocare AB
37677	Implant Driver Conical Connection NP for Slim Abutment	Ila	Rule 6	2014-10-08	2797	Nobel Biocare AB
37678	Implant Driver Conical Connection RP for Slim Abutment	Ila	Rule 6	2014-10-08	2797	Nobel Biocare AB
37713	Implant Driver Conical Connection 3.0 for Slim Abutment	Ila	Rule 6	2014-10-08	2797	Nobel Biocare AB
37766	NobelZygoma™ 0° Twist Drill 2.9mm	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37767	NobelZygoma™ 0° Twist Drill 2.9mm Short	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37768	NobelZygoma™ 0° Twist Drill 3.5mm	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37769	NobelZygoma™ 0° Twist Drill 3.5mm Short	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37770	NobelZygoma™ 0° Twist Drill 4.0mm	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37771	NobelZygoma™ 0° Twist Drill 4.0mm Short	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37772	NobelZygoma™ 0° Twist Drill 4.4mm	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37773	NobelZygoma™ 0° Twist Drill 4.4mm Short	Ila	Rule 6	2015-12-07	2797	Nobel Biocare AB
37859	Implant Driver Conical Connection WP 28mm	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37860	Implant Driver Conical Connection WP 37mm	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37861	Bone Mill with Guide Conical Connection 3.0 Ø4.0	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37863	Bone Mill with Guide Conical Connection NP Ø4.4	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37864	Bone Mill with Guide Conical Connection NP Ø5.2	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37866	Bone Mill with Guide Conical Connection RP Ø5.2	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37867	Bone Mill with Guide Conical Connection RP Ø6.2	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37869	Bone Mill with Guide Conical Connection WP Ø6.7	Ila	Rule 6	2015-02-26	2797	Nobel Biocare AB
37873	Twist Step Drill 2.8/3.2 7-10mm	Ila	Rule 6	2014-10-27	2797	Nobel Biocare AB
37874	Twist Step Drill 4.2/4.6 7-10mm	Ila	Rule 6	2014-10-27	2797	Nobel Biocare AB
37875	Twist Step Drill 4.2/5.0 7-10mm	Ila	Rule 6	2014-10-27	2797	Nobel Biocare AB
37876	Twist Step Drill 4.2/5.0 7-15mm	Ila	Rule 6	2014-10-27	2797	Nobel Biocare AB
37927	Implant Retrieval Instrument CC WP 22mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37928	Trephine Drill 3.8/4.6mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37929	Trephine Drill 4.4/5.2mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37930	Trephine Drill 5.2/6.2mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37931	Trephine Drill 5.6/6.6mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37932	Trephine Drill 6.2/7.0mm	Ila	Rule 6	2015-03-24	2797	Nobel Biocare AB
37934	Guided Twist Step Drill 4.2/5.0 (10+) 7-13mm	Ila	Rule 6	2015-02-10	2797	Nobel Biocare AB
37945	Guided Twist Step Drill 4.2/5.0 (10+) 7-18mm	Ila	Rule 6	2015-02-10	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.



Document type
DOC

Document no.
131506

Part
000

Version
26

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
37946	Guided Screw Tap NobelActive® WP 5.5 7-8.5mm	Ila	Rule 6	2015-02-10	2797	Nobel Biocare AB
37947	Guided Screw Tap NobelActive® WP 5.5 10-15mm	Ila	Rule 6	2015-02-10	2797	Nobel Biocare AB
37990	Screw Tap NobelParallel™ CC 3.75 7-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37991	Screw Tap NobelParallel™ CC 3.75 7-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37992	Screw Tap NobelParallel™ CC 4.3 7-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37993	Screw Tap NobelParallel™ CC 4.3 7-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37994	Screw Tap NobelParallel™ CC 5.0 7-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37995	Screw Tap NobelParallel™ CC 5.0 7-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37996	Screw Tap NobelParallel™ CC 5.5 7-10mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
37997	Screw Tap NobelParallel™ CC 5.5 7-15mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38000	NobelParallel™ CC Cortical Drill 3.75mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38001	NobelParallel™ CC Cortical Drill 4.3mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38002	NobelParallel™ CC Cortical Drill 5.0mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38003	NobelParallel™ CC Cortical Drill 5.5mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38045	Guided Twist Step Drill Ø4.2/4.6 (10+) 7-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38047	Guided Screw Tap NobelParallel™ CC 3.75 7-10mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38048	Guided Screw Tap NobelParallel™ CC 3.75 11.5-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38049	Guided Screw Tap NobelParallel™ CC 3.75 15-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38050	Guided Screw Tap NobelParallel™ CC 4.3 7-10mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38051	Guided Screw Tap NobelParallel™ CC 4.3 11.5-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38052	Guided Screw Tap NobelParallel™ CC 4.3 15-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38053	Guided Screw Tap NobelParallel™ CC 5.0 7-10mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38054	Guided Screw Tap NobelParallel™ CC 5.0 11.5-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38055	Guided Screw Tap NobelParallel™ CC 5.0 15-18mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38056	Guided Screw Tap NobelParallel™ CC 5.5 7-10mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38057	Guided Screw Tap NobelParallel™ CC 5.5 11.5-13mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38058	Guided Screw Tap NobelParallel™ CC 5.5 11.5-15mm	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38059	Guided Tissue Punch for NP-sleeve (3.75)	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38060	Guided Tissue Punch for WP/6.0-sleeve (5.5)	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38061	Guided Counterbore NobelParallel™ CC 3.75	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38062	Guided Counterbore NobelParallel™ CC 4.3	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38063	Guided Counterbore NobelParallel™ CC 5.0	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.

Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
38064	Guided Counterbore NobelParallel™ CC 5.5	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38065	Guided Implant Mount NobelParallel™ CC NP	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38066	Guided Implant Mount NobelParallel™ CC RP 4.3	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38067	Guided Implant Mount NobelParallel™ CC RP 5.0	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38068	Guided Implant Mount NobelParallel™ CC WP 5.5	Ila	Rule 6	2014-12-11	2797	Nobel Biocare AB
38179	Guided Dense Bone Screw Tap NobelActive® NP 8.5-18 mm	Ila	Rule 6	2015-03-26	2797	Nobel Biocare AB
38180	Guided Dense Bone Screw Tap NobelActive® RP 4.3 8.5-18 mm	Ila	Rule 6	2015-03-26	2797	Nobel Biocare AB
38181	Guided Dense Bone Screw Tap NobelActive® RP 5.0 8.5-18 mm	Ila	Rule 6	2015-03-26	2797	Nobel Biocare AB
38182	Guided Dense Bone Screw Tap NobelActive® WP 5.5 7-8.5 mm	Ila	Rule 6	2015-03-26	2797	Nobel Biocare AB
38183	Guided Dense Bone Screw Tap NobelActive® WP 5.5 10-15 mm	Ila	Rule 6	2015-03-26	2797	Nobel Biocare AB
38324	Twist Drill Trefoil™ 2x11.5-13mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38335	Twist Drill Trefoil™ 3x11.5-13mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38336	Twist Drill Trefoil™ 3.8x11.5-13mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38337	Twist Drill Trefoil™ 4.2x11.5-13mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38338	Twist Drill Trefoil™ 4.4x11.5-13mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38339	Screw Tap Trefoil™ 5.0 mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38340	Implant Mount Ø5mm	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38359	Transfer Abutment	Ila	Rule 6	2015-10-22	2797	Nobel Biocare AB
38752	On1 Screwdriver Machine 21mm	Ila	Rule 6	2016-06-15	2797	Nobel Biocare AB
300852	Screwdriver Machine Omnigrip™ Mini 20mm	Ila	Rule 6	2019-12-19	2797	Nobel Biocare AB
300853	Screwdriver Machine Omnigrip™ Mini 28mm	Ila	Rule 6	2019-12-19	2797	Nobel Biocare AB
300854	Screwdriver Machine Omnigrip™ Mini 36mm	Ila	Rule 6	2019-12-19	2797	Nobel Biocare AB
300905	Implant Driver Nobel Biocare N1™ TCC NP Short	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300906	Implant Driver Nobel Biocare N1™ TCC NP Long	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300907	Implant Driver Nobel Biocare N1™ TCC RP Short	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300908	Implant Driver Nobel Biocare N1™ TCC RP Long	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300909	Bone Mill Nobel Biocare N1™ TCC Ø4.0	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300910	Bone Mill Nobel Biocare N1™ TCC Ø5.2	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300923	OsseoShaper Extension Nobel Biocare N1™	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
301151	Screw Tap Repair Tool Nobel Biocare N1™ TCC NP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
301152	Screw Tap Repair Tool Nobel Biocare N1™ TCC RP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
301294	Implant Retrieval Instrument CC 3.0 & TCC NP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.



Document type Document no. Part Version
DOC **131506** **000** **26**

Material	Description	Class	Rule	Date added	Notified Body No.	Legal Manufacturer
301295	Implant Retrieval Instrument CC RP & Tri-Ch WP & TCC RP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
301296	Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
301297	Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP	Ila	Rule 6	2020-05-04	2797	Nobel Biocare AB
300903	Screwdriver Machine Nobel Biocare N1™ Base 28mm	Ila	Rule 6	2020-11-26	2797	Nobel Biocare AB
300904	Screwdriver Machine Nobel Biocare N1™ Base 36mm	Ila	Rule 6	2020-11-26	2797	Nobel Biocare AB

Confidential and proprietary.

This document and its contents are confidential and proprietary to Nobel Biocare and shall not be reproduced or otherwise disclosed to anyone other than Nobel Biocare employees without written authorization from Nobel Biocare.