

MANUFACTURER'S SELF DECLARATION

Considering the Regulation (EU) 2023/607 amending Regulations (EU) 2017 /745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Notified body has approved the extension. Therefore, the devices will be available for sale after May 26, 2024.

Notified body Confirmation Letter No.: 150293209

The class IIa devices under MDD EC Certificate (HD 60148508 0001) can be legally placed on the market and used until December 31, 2028.

MANUFACTURER

NAKANISHI INC.

700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

Single Registration Number(SRN): JP-MF-000011271

Registered Trade Name: NAKANISHI INC.

Registered Trade Mark: NSK

Notified body: TÜV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nürnberg,
Germany

Notified Body number: 0197

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH

Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

Single Registration Number(SRN): DE-AR-000007040

MEDICAL DEVICE

EMDN Code See No. 287-20240508-01 002 Attachment 1

Basic UDI-DI: See No. 287-20240508-01 002 Attachment 1

Product Name: See No. 287-20240508-01 002 Attachment 1

Classification (MDR): See No. 287-20240508-01 002 Attachment 1

MDD EC Certificate Registration No.: HD 60148508 0001

Declare under our sole responsibility that:

- The devices listed below continue to comply with the Medical Device Directive 93/42/EEC.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- The MDD EC certificate covering the devices was valid after May 26th 2021 and has not been suspended nor withdrawn afterwards.
- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- Requirements of regulation (EU) 2017/745 relating to post-market surveillance and registration of economic operators are met.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

Tochigi, Japan: 2024-05-30

Place, Date

Masaaki Kikuchi

Person Responsible for Regulatory Compliance

NAKANISHI INC.

No.	Model or Type	Name	General Product Group Name	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Device Class (MDR)	Classification Rule including subclause according to Annex VIII
1	X-DSG20	Ti-Max X-DSG20	Line-powered dental drilling system handpiece	4560224980000036P	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
1	X-DSG20L	Ti-Max X-DSG20	Line-powered dental drilling system handpiece	4560224980000036P	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
1	X-DSG20h	Ti-Max X-DSG20	Line-powered dental drilling system handpiece	4560224980000036P	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
1	X-DSG20Lh	Ti-Max X-DSG20	Line-powered dental drilling system handpiece	4560224980000036P	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
2	Perio Mate Powder	Perio Mate Powder	Dental abrasive powder	4560224980000046R	MDN T209 Non-active non-implantable dental materials	Q010104	IIa	rule 6, first paragraph
3	PER-PTL-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-KV-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-SR-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-WH-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-BA-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-M4-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
3	PER-B2-P	Perio-Mate Kit	Dental abrasive air jet system handpiece	456022498000002775	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
4	Surgic Pro	Surgic Pro	Dental implant system	456022498000002877	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
5	Surgic Pro2	Surgic Pro2	Dental implant system	45602249800000056T	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800L	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900L	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800KL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900KL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800SL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900SL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800BL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900BL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800WL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900WL	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800K	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900K	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z800W	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
7	Z900W	Ti-Max Z	Pneumatic dental drilling system handpiece	456022498000002979	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2 QD	Pana-Max2	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2 M4	Pana-Max2	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2 B2	Pana-Max2	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2 PTL	Pana-Max2	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2 KV	Pana-Max2	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph

No.	Model or Type	Name	General Product Group Name	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Device Class (MDR)	Classification Rule including subclause according to Annex VIII
10	Pana-Max2R M4	Pana-Max2R	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
10	Pana-Max2R B2	Pana-Max2R	Pneumatic dental drilling system handpiece	45602249800000326W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-MU B2	Pana-Max PLUS2 MU B2	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-MU M4	Pana-Max PLUS2 MU M4	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-MU QD	Pana-Max PLUS2 MU QD	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-SU B2	Pana-Max PLUS2 SU B2	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-SU M4	Pana-Max PLUS2 SU M4	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
11	PAP2-SU QD	Pana-Max PLUS2 SU QD	Pneumatic dental drilling system handpiece	45602249800000336Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-MU B2	Pana-Max PLUS MU B2	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-MU M4	Pana-Max PLUS MU M4	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-QD MU	Pana-Max PLUS QD MU	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-SU B2	Pana-Max PLUS SU B2	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-SU M4	Pana-Max PLUS SU M4	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
12	PAP-QD SU	Pana-Max PLUS QD SU	Pneumatic dental drilling system handpiece	456022498000003472	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
13	PAF-SU M4	PanaAir FX	Pneumatic dental drilling system handpiece	456022498000003574	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
13	PAF-SU B2	PanaAir FX	Pneumatic dental drilling system handpiece	456022498000003574	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
13	PAF-SU QD	PanaAir FX	Pneumatic dental drilling system handpiece	456022498000003574	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
13	PAF-S M4	PanaAir FX	Pneumatic dental drilling system handpiece	456022498000003574	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
13	PAF-S B2	PanaAir FX	Pneumatic dental drilling system handpiece	456022498000003574	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-MU M4	FX Plus MU M4	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-SU M4	FX Plus SU M4	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-MU B2	FX Plus MU B2	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-SU B2	FX Plus SU B2	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-MU QD	FX Plus MU QD	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
14	FXP-SU QD	FX Plus SU QD	Pneumatic dental drilling system handpiece	456022498000003676	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
15	S-Max pico	S-Max pico	Pneumatic dental drilling system handpiece	456022498000003778	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
15	S-Max pico KL	S-Max pico	Pneumatic dental drilling system handpiece	456022498000003778	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
15	S-Max pico M4	S-Max pico	Pneumatic dental drilling system handpiece	456022498000003778	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
15	S-Max pico B2	S-Max pico	Pneumatic dental drilling system handpiece	456022498000003778	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
15	S-Max pico QD	S-Max pico QD	Pneumatic dental drilling system handpiece	456022498000003778	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
16	M500LG M4	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
16	M600LG M4	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
16	M500LG B2	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
16	M600LG B2	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph

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16	M500LG QD	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
16	M600LG QD	DynaLED	Pneumatic dental drilling system handpiece	45602249800000387A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800L	S-Max M800L	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900L	S-Max M900L	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800	S-Max M800	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900	S-Max M900	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800KL	S-Max M800KL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900KL	S-Max M900KL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900K	S-Max M900K	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800SL	S-Max M800SL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900SL	S-Max M900SL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800BL	S-Max M800BL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900BL	S-Max M900BL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M800WL	S-Max M800WL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900WL	S-Max M900WL	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
17	M900W	S-Max M900W	Pneumatic dental drilling system handpiece	45602249800000397C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
18	Z micro	Ti-Max Z	Pneumatic dental drilling system handpiece	45602249800000406V	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
18	Z micro KL	Ti-Max Z	Pneumatic dental drilling system handpiece	45602249800000406V	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
18	Z micro SL	Ti-Max Z	Pneumatic dental drilling system handpiece	45602249800000406V	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
19	M micro	S-Max M micro	Pneumatic dental drilling system handpiece	45602249800000416X	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
19	M micro KL	S-Max M micro KL	Pneumatic dental drilling system handpiece	45602249800000416X	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
19	M micro SL	S-Max M micro SL	Pneumatic dental drilling system handpiece	45602249800000416X	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450L	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450KL	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450SL	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450QD	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
20	X450 M4	Ti-Max X450	Pneumatic dental drilling system handpiece	45602249800000426Z	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
21	X12	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X15	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X15L	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X20L	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X25	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X25L	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph

No.	Model or Type	Name	General Product Group Name	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Device Class (MDR)	Classification Rule including subclause according to Annex VIII
21	X95	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X95L	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X85	Ti-Max X	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	Z95L	Ti-Max Z	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	Z85L	Ti-Max Z	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	Z25L	Ti-Max Z	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	Z15L	Ti-Max Z	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	Z24L	Ti-Max Z	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	X95EX	Ti-Max X95EX	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	nano95LS	Ti-Max nano95LS	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	nano25LS	Ti-Max nano25LS	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
21	nano15LS	Ti-Max nano15LS	Dental drilling system attachment	456022498000004373	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M15	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M15L	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M25	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M25L	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M95	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
22	M95L	S-Max M	Dental drilling system attachment	456022498000004577	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
23	E205IL	E205IL	Dental drilling system attachment	456022498000004679	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
24	E200IL	E200IL	Dental drilling system attachment	45602249800000477B	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX15	FX15	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX23	FX23	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX25	FX25	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX15m	FX15m	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX25m	FX25m	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
25	FX22	FX22	Dental drilling system attachment	45602249800000487D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
27	FFB-EC	FFB	Dental drilling system attachment	45602249800000506Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
28	FFB-ECM	FFB	Dental drilling system attachment	456022498000005172	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
29	FPB-EC	FPB	Dental drilling system attachment	456022498000005274	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
30	FPB-ECM	FPB	Dental drilling system attachment	456022498000005376	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
31	NAC-EC	NAC	Dental drilling system attachment	456022498000005478	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
32	NAC-ER16	NAC	Dental drilling system attachment	45602249800000557A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
33	NBB-EC	NBB	Dental drilling system attachment	45602249800000567C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph

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34	NBBW-EC	NBBW	Dental drilling system attachment	45602249800000577E	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
35	BB-EC	BB	Dental drilling system attachment	45602249800000587G	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
36	X65	Ti-Max X	Dental drilling system attachment	45602249800000597J	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
36	X65L	Ti-Max X	Dental drilling system attachment	45602249800000597J	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
36	nano65LS	Ti-Max nano65LS	Dental drilling system attachment	45602249800000597J	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
37	M65	S-Max M65	Dental drilling system attachment	456022498000006073	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
38	E400I	E400I	Dental drilling system attachment	456022498000006175	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
39	EX-6B	EX-6	Dental drilling system attachment	456022498000006277	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
40	EX-5B	EX-5	Dental drilling system attachment	456022498000006379	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
41	FX65	FX65	Dental drilling system attachment	45602249800000647B	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
41	FX65m	FX65m	Dental drilling system attachment	45602249800000647B	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
43	X35	Ti-Max X	Dental drilling system attachment	45602249800000667F	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
43	X35L	Ti-Max X	Dental drilling system attachment	45602249800000667F	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
44	Ti-ENDO	Ti-ENDO	Dental drilling system attachment	45602249800000677H	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
45	FX75	FX75	Dental drilling system attachment	45602249800000687K	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
45	FX75m	FX75m	Dental drilling system attachment	45602249800000687K	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
46	MPA-ER16	MPA	Dental drilling system attachment	45602249800000697M	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
47	MPA-ER64	MPA	Dental drilling system attachment	456022498000007076	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
48	MPAS-ER16	MPAS	Dental drilling system attachment	456022498000007178	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
49	MPAS-ER64	MPAS	Dental drilling system attachment	45602249800000727A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
50	MP-ER16	MP	Dental drilling system attachment	45602249800000737C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
51	MP-ER64	MP	Dental drilling system attachment	45602249800000747E	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
52	NM-EC	NM	Dental drilling system attachment	45602249800000767J	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
53	NRS2-EC	NRS2	Dental drilling system attachment	45602249800000777L	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
54	NRS2-ECM	NRS2	Dental drilling system attachment	45602249800000787N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
55	NRS2-ER10	NRS2	Dental drilling system attachment	45602249800000797Q	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
56	TEP-ER10	TEP	Dental drilling system attachment	45602249800000817B	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
57	TEQ-E10R	TEQ	Dental drilling system attachment	45602249800000827D	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
58	VM-E4R	VM	Dental drilling system attachment	45602249800000837F	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
59	Z45L	Ti-Max Z45L	Dental drilling system attachment	45602249800000847H	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 5, second paragraph
60	SG20	SG20	Line-powered dental drilling system handpiece	45602249800000857K	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
60	SG20M	S-Max	Line-powered dental drilling system handpiece	45602249800000857K	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
61	X-SG20L	X-SG	Line-powered dental drilling system handpiece	45602249800000867M	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph

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61	X-SG20ML	Ti-Max X	Line-powered dental drilling system handpiece	45602249800000867M	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
63	SGM-ER16i	SGM	Line-powered dental drilling system handpiece	45602249800000887R	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
64	SGM-ER20i	SGM	Line-powered dental drilling system handpiece	45602249800000897T	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
65	SGMS-ER20i	SGMS	Line-powered dental drilling system handpiece	45602249800000907C	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
66	SGS-ES	SGS	Line-powered dental drilling system handpiece	45602249800000917E	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
67	SGS-E2S	SGS	Line-powered dental drilling system handpiece	45602249800000927G	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
68	SGA-E2S	SGA	Line-powered dental drilling system handpiece	45602249800000937J	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
69	SGA-ES	SGA	Line-powered dental drilling system handpiece	45602249800000947L	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
70	X-SG65L	Ti-Max X-SG	External Coolant Straight Handpiece for foot surgery and oral surgery	45602249800000957N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
70	X-SG65	Ti-Max X-SG	External Coolant Straight Handpiece for foot surgery and oral surgery	45602249800000957N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
71	Z-SG45L	Ti-Max Z-SG45L	Line-powered dental drilling system handpiece	45602249800000967Q	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
71	Z-SG45	Ti-Max Z-SG45	Line-powered dental drilling system handpiece	45602249800000967Q	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
72	X-SG25L	X-SG	Line-powered dental drilling system handpiece	45602249800000977S	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
73	X-SG93	Ti-Max X-SG	Line-powered dental drilling system handpiece	45602249800000987U	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
73	X-SG93L	Ti-Max X-SG	Line-powered dental drilling system handpiece	45602249800000987U	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
74	SGX-E20R	SGX	Dental drilling system attachment	45602249800000997W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 6, first paragraph
75	FX205 B2	FX205 B2	Air Motor	45602249800001006N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
75	FX205 M4	FX205 M4	Air Motor	45602249800001006N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
75	FX204 M4	FX204 M4	Air Motor	45602249800001006N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
75	FX205m B2	FX205m B2	Air Motor	45602249800001006N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
75	FX205m M4	FX205m M4	Air Motor	45602249800001006N	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
76	M205	S-Max M205	Air Motor	45602249800001016Q	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
77	X205L	Ti-Max X205L	Air Motor	45602249800001026S	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
79	VIVA ace	VIVA ace	Dental suction system, non-surgical	45602249800001046W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph

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92	Ti-Max NLX nano	Ti-Max NLX nano	Remotely-driven dental drilling system motor	456022498000011879	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
93	Ti-Max NLX plus	Ti-Max NLX plus	Remotely-driven dental drilling system motor	45602249800001197B	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
94	NLZ	NLZ	Remotely-driven dental drilling system motor	45602249800001206U	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
94	NLZ Endo	NLZ Endo	Dental drilling system Attachment	45602249800001206U	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
94	NLZ BF	NLZ BF	Remotely-driven dental drilling system motor	45602249800001206U	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
95	NLZ BF	NLZ BF	Remotely-driven dental drilling system motor	45602249800001216W	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	NBX	NBX	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	NBX N	NBX	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	M40XS	M40XS	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	M40N XS	M40XS	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	iMD	iMD	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
96	iMD BS	iMD	Remotely-driven dental drilling system motor	45602249800001226Y	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
97	VIVAMATE G5	VIVAMATE G5	Remotely-driven dental drilling system motor	456022498000012372	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MP-F10R	MP	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MP-F16R	MP	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MP-F20R	MP	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MPA-F16R	MPA	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MPAS-F16R	MPAS	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	MPAS-F20R	MPAS	Dental drilling system attachment	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
98	ENDO-MATE TC2 Set	ENDO-MATE TC2 Set	Endodontic enlarger	456022498000012474	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
99	ENDO-MATE DT	ENDO-MATE DT	Endodontic enlarger	456022498000012576	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
100	ENDO-MATE DT2	ENDO-MATE DT2	Endodontic enlarger	456022498000012678	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
101	iProphy	iProphy	Dental-professional prophylaxis motor	45602249800001277A	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
103	Straumann Surgical Motor Pro	Straumann Surgical Motor Pro	Dental implant system	45602249800001297E	MDA 0311 Active non-implantable dental devices	Z121101	IIa	rule 9, first paragraph
104	X57	Ti-Max X	Dental drilling system attachment	45602249800001306X	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
104	X57L	Ti-Max X	Dental drilling system attachment	45602249800001306X	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
105	FX57	FX57	Dental drilling system attachment	45602249800001316Z	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
105	FX57m	FX57m	Dental drilling system attachment	45602249800001316Z	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph

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106	AR-ER10(S)	AR	Dental drilling system attachment	456022498000013273	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
107	AR-EC(S)	AR	Dental drilling system attachment	456022498000013375	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
108	AR-ECM(S)	AR	Dental drilling system attachment	456022498000013477	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
109	AR-ER4(S)	AR	Dental drilling system attachment	456022498000013579	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
110	AR-ER4M(S)	AR	Dental drilling system attachment	45602249800001367B	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
111	AR-EC(K)	AR	Dental drilling system attachment	45602249800001377D	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
112	AR-ECM(K)	AR	Dental drilling system attachment	45602249800001387F	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
113	X55	Ti-Max X	Dental drilling system attachment	45602249800001397H	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
113	X55L	Ti-Max X	Dental drilling system attachment	45602249800001397H	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
114	EVA-ER4	EVA	Dental drilling system attachment	456022498000014072	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
115	EVA-ER4M	EVA	Dental drilling system attachment	456022498000014174	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 5, second paragraph
116	S970L	Ti-Max S970	Pneumatic dental scaling system handpiece	456022498000014276	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
116	S970KL	Ti-Max S970	Pneumatic dental scaling system handpiece	456022498000014276	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
116	S970SL	Ti-Max S970	Pneumatic dental scaling system handpiece	456022498000014276	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
116	S970	Ti-Max S970	Pneumatic dental scaling system handpiece	456022498000014276	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
117	AS2000 B2/3	AS2000	Pneumatic dental scaling system handpiece	456022498000014378	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
118	AS2000 M4	AS2000	Pneumatic dental scaling system handpiece	45602249800001447A	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
119	Varios Combi Pro	Varios Combi Pro	Ultrasonic dental scaling system, Dental abrasive air jet system handpiece	45602249800001457C	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMN-HP	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-PTL-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-M4-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-B2-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-KV-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-WH-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-BA-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-SR-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
120	PMNG-QD-P	Prophy-Mate neo	Dental abrasive air jet system handpiece	45602249800001467E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
121	SGO2-E	SGO2-E	Sawing power tool attachment, oscillating	45602249800001477G	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 6, first paragraph
122	SGR2-E	SGR2-E	Sawing power tool attachment, reciprocating	45602249800001487J	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 6, first paragraph
123	SGT2-E	SGT2-E	Sawing power tool attachment, sagittal	45602249800001497L	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 6, first paragraph
124	Varios 970	Varios 970	Ultrasonic dental scaling system	456022498000015075	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
125	Varios 970	Varios 970	Ultrasonic dental scaling system	456022498000015177	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
126	Varios 970	Varios 970	Ultrasonic dental scaling system	456022498000015279	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
127	Varios 970 LUX	Varios 970 LUX	Ultrasonic dental scaling system	45602249800001537B	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph

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128	Varios 970 LUX	Varios 970 LUX	Ultrasonic dental scaling system	45602249800001547D	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
129	Varios 170	Varios 170	Ultrasonic dental scaling system	45602249800001557F	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
130	Varios 170	Varios 170	Ultrasonic dental scaling system	45602249800001567H	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
131	Varios 170	Varios 170	Ultrasonic dental scaling system	45602249800001577K	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
132	Varios 170	Varios 170	Ultrasonic dental scaling system	45602249800001587M	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
133	Varios 170	Varios 170	Ultrasonic dental scaling system	45602249800001597P	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
134	Varios 170	Varios 170	Ultrasonic dental scaling system	456022498000016078	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
135	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001617A	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
136	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001627C	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
137	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001637E	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
138	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001647G	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
139	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001657J	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
140	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001667L	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
141	Varios 170 LUX	Varios 170 LUX	Ultrasonic dental scaling system	45602249800001677N	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
142	Varios 370	Varios 370	Ultrasonic dental scaling system	45602249800001687Q	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
143	Varios 370	Varios 370	Ultrasonic dental scaling system	45602249800001697S	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
144	Varios 370 Lux	Varios 370 Lux	Ultrasonic dental scaling system	45602249800001707B	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
145	VA370 LUX	Varios 370 Lux	Ultrasonic dental scaling system	45602249800001717D	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
146	VarioSurg 3	VarioSurg 3	Dental ultrasonic surgical system	45602249800001727F	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
147	VarioSurg 3	VarioSurg 3	Dental ultrasonic surgical system	45602249800001737H	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
148	VarioSurg 3	VarioSurg 3	Dental ultrasonic surgical system	45602249800001747K	MDA 0311 Active non-implantable dental devices	Z121190	IIa	rule 9, first paragraph
149	S1	S1	Pneumatic dental scaling system handpiece tip	45602249800001757M	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
149	S2	S2	Pneumatic dental scaling system handpiece tip	45602249800001757M	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
149	S3	S3	Pneumatic dental scaling system handpiece tip	45602249800001757M	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
150	S10	S10	Pneumatic dental scaling system handpiece tip	45602249800001767P	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
150	S20	S20	Pneumatic dental scaling system handpiece tip	45602249800001767P	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
150	S21R	S21R	Pneumatic dental scaling system handpiece tip	45602249800001767P	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
150	S21L	S21L	Pneumatic dental scaling system handpiece tip	45602249800001767P	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
151	V-P10	V-P10	Ultrasonic dental scaling system handpiece tip	45602249800001777R	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
151	V-P12	V-P12	Ultrasonic dental scaling system handpiece tip	45602249800001777R	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
151	V-P11R	V-P11R	Ultrasonic dental scaling system handpiece tip	45602249800001777R	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph
151	V-P11L	V-P11L	Ultrasonic dental scaling system handpiece tip	45602249800001777R	MDN 1208 Non-active non-implantable instruments	Z121190	IIa	rule 5, second paragraph

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151	S35	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001777R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S65D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S66D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S67D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S68D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S71D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S72D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S81D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S82D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S83D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
152	S86D	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001787T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
153	S75	S75	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
153	V-U15	V-U15	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
153	V-U20	V-U20	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
153	V-U25	V-U25	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
153	V-U30	V-U30	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
153	V-U35	V-U35	Pneumatic dental scaling system handpiece tip	45602249800001797V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
154	PMN-PTL	FLASH Pearl	Dental abrasive powder	45602249800001807E	MDN 1209 Non-active non-implantable dental materials	Q010104	Ila	rule 5, second paragraph
155	G1	G1	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G1-E	G1-E	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G2	G2	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G2-E	G2-E	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G3	G3	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G3-E	G3-E	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G4	G4	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G4-E	G4-E	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G5	G5	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G6	G6	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph

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155	G6-E	G6-E	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G11	G11	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G12	G12	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G13	G13	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G8	G8	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G9	G9	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
155	G16	G16	Ultrasonic dental scaling system handpiece tip	45602249800001817G	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P1	P1	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P1D	P1D	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P10	P10	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P2D	P2D	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P3D	P3D	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P20	P20	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P20-E	P20-E	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P21R	P21R	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P21R-E	P21R-E	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P21L	P21L	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P21L-E	P21L-E	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P25R	P25R	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P25R-E	P25R-E	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P25L	P25L	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P25L-E	P25L-E	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P40	P40	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P41	P41	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P26R	P26R	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P26L	P26L	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
156	P11R	P11R	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph

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156	P11L	P11L	Ultrasonic dental scaling system handpiece tip	45602249800001827J	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V10	V10	Ultrasonic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P26R	V-P26R	Ultrasonic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P26L	V-P26L	Ultrasonic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P10	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P11R	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P11L	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
157	V-P12	NSK Air Scaler Tip	Pneumatic dental scaling system handpiece tip	45602249800001837L	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
158	V30	V30	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	V-G70	V-G70	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	V-G71	V-G71	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	V-G72	V-G72	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	V-G75	V-G75	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	V-G76	V-G76	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G61D	G61D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G62D	G62D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G65D	G65D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G66D	G66D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G67D	G67D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G68D	G68D	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
158	G95	G95	Ultrasonic dental scaling system handpiece tip	45602249800001847N	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
159	V-G78	V-G78	Ultrasonic dental scaling system handpiece tip	45602249800001857Q	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
159	V-G79	V-G79	Ultrasonic dental scaling system handpiece tip	45602249800001857Q	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, second paragraph
160	E30RD	E30RD	Ultrasonic dental scaling system handpiece tip	45602249800001867S	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
160	E30LD	E30LD	Ultrasonic dental scaling system handpiece tip	45602249800001867S	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
160	E31D	E31D	Ultrasonic dental scaling system handpiece tip	45602249800001867S	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
160	E32D	E32D	Ultrasonic dental scaling system handpiece tip	45602249800001867S	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG1	SG1	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph

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161	SG2R	SG2R	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG2L	SG2L	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG3	SG3	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG4	SG4	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG5	SG5	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG6D	SG6D	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG7D	SG7D	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG8	SG8	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG14R	SG14R	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG14L	SG14L	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG19	SG19	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG1A	SG1A	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG8A	SG8A	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG30	SG30	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG58	SG58	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	H-SG1	H-SG1	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	H-SG8	H-SG8	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	SG68	SG68	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	H-SG8R	H-SG8R	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
161	H-SG8L	H-SG8L	Dental ultrasonic surgical system handpiece tip	45602249800001877U	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SG9	SG9	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SG10	SG10	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SG11	SG11	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SCL1	SCL1	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SCL3	SCL3	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
162	SCL5	SCL5	Dental ultrasonic surgical system handpiece tip	45602249800001887W	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph

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163	SG17	SG17	Dental ultrasonic surgical system handpiece tip	45602249800001897Y	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
163	SG18R	SG18R	Dental ultrasonic surgical system handpiece tip	45602249800001897Y	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
163	SG18L	SG18L	Dental ultrasonic surgical system handpiece tip	45602249800001897Y	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
164	G1-S	G1-S	Dental ultrasonic surgical system handpiece tip	45602249800001907H	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
165	V10-S	V10-S	Dental ultrasonic surgical system handpiece tip	45602249800001917K	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
165	V-P10	V-P10	Ultrasonic dental scaling system handpiece tip	45602249800001917K	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
165	V-P12	V-P12	Ultrasonic dental scaling system handpiece tip	45602249800001917K	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
165	V-P11R	V-P11R	Ultrasonic dental scaling system handpiece tip	45602249800001917K	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
165	V-P11L	V-P11L	Ultrasonic dental scaling system handpiece tip	45602249800001917K	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
166	E30RD-S	E30RD-S	Dental ultrasonic surgical system handpiece tip	45602249800001927M	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
166	E30LD-S	E30LD-S	Dental ultrasonic surgical system handpiece tip	45602249800001927M	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
166	E31D-S	E31D-S	Dental ultrasonic surgical system handpiece tip	45602249800001927M	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
166	E32D-S	E32D-S	Dental ultrasonic surgical system handpiece tip	45602249800001927M	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
167	P20-S	P20-S	Dental ultrasonic surgical system handpiece tip	45602249800001937P	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
167	P25R-S	P25R-S	Dental ultrasonic surgical system handpiece tip	45602249800001937P	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
167	P25L-S	P25L-S	Dental ultrasonic surgical system handpiece tip	45602249800001937P	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 5, first paragraph
168	SG15A	SG15A	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SG15B	SG15B	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SG16A	SG16A	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SG16B	SG16B	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SG15C	SG15C	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SG15D	SG15D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SCL1D	SCL1D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SCL2D	SCL2D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SCL4D	SCL4D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SCL3D	SCL3D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
168	SCL5D	SCL5D	Dental ultrasonic surgical system handpiece tip	45602249800001947R	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph

No.	Model or Type	Name	General Product Group Name	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Device Class (MDR)	Classification Rule including subclause according to Annex VIII
169	E4	E4	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E4D	E4D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E7D	E7D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E8D	E8D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E11	E11	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E12	E12	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	U files 33mm ISO 15	U files 33mm ISO 15	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	U files 33mm ISO 20	U files 33mm ISO 20	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	U files 33mm ISO 25	U files 33mm ISO 25	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	U files 33mm ISO 30	U files 33mm ISO 30	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	U files 33mm ISO 35	U files 33mm ISO 35	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S50	V-S50	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S51	V-S51	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S52	V-S52	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S53	V-S53	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S51D	V-S51D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S52D	V-S52D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	V-S53D	V-S53D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E15D	E15D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E9	E9	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E9D	E9D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
169	E14D	E14D	Ultrasonic dental scaling system handpiece tip	45602249800001957T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
170	SGO-1	SGO	Oscillating surgical saw blade, reusable	45602249800001967V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
171	SGO-2	SGO	Oscillating surgical saw blade, reusable	45602249800001977X	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
172	SGO-3	SGO	Oscillating surgical saw blade, reusable	45602249800001987Z	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
173	SGO-4	SGO	Oscillating surgical saw blade, reusable	456022498000019983	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
174	SGO-5	SGO	Oscillating surgical saw blade, reusable	45602249800002006T	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph
175	SGO-6	SGO	Oscillating surgical saw blade, reusable	45602249800002016V	MDN 1208 Non-active non-implantable instruments	Z121190	Ila	rule 6, first paragraph

No.	Model or Type	Name	General Product Group Name	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Device Class (MDR)	Classification Rule including subclause according to Annex VIII
176	E7	E7	Ultrasonic dental scaling system handpiece tip	45602249800002026X	MDN 1208 Non-active non-implantable instruments	Z121101	Ila	rule 6, first paragraph
176	E8	E8	Ultrasonic dental scaling system handpiece tip	45602249800002026X	MDN 1208 Non-active non-implantable instruments	Z121101	Ila	rule 6, first paragraph
176	E5	E5	Ultrasonic dental scaling system handpiece tip	45602249800002026X	MDN 1208 Non-active non-implantable instruments	Z121101	Ila	rule 6, first paragraph
176	E6	E6	Ultrasonic dental scaling system handpiece tip	45602249800002026X	MDN 1208 Non-active non-implantable instruments	Z121101	Ila	rule 6, first paragraph
177	iPex II	iPex II	Endodontic apex locator	45602249800002036Z	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 10, first paragraph
178	SGR-1	SGR	Reciprocating surgical saw blade, reusable	456022498000020473	MDN 1208 Non-active non-implantable instruments	L0103	Ila	rule 6, first paragraph
179	SGR-2	SGR	Reciprocating surgical saw blade, reusable	456022498000020575	MDN 1208 Non-active non-implantable instruments	L0103	Ila	rule 6, first paragraph
180	SGR-3	SGR	Reciprocating surgical saw blade, reusable	456022498000020677	MDN 1208 Non-active non-implantable instruments	L0103	Ila	rule 6, first paragraph
181	SGT-1	SGT	Sagittal surgical saw blade, reusable	456022498000020779	MDN 1208 Non-active non-implantable instruments	Z129080	Ila	rule 6, first paragraph
182	SGT-2	SGT	Sagittal surgical saw blade, reusable	45602249800002087B	MDN 1208 Non-active non-implantable instruments	Z129080	Ila	rule 6, first paragraph
183	PC1	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC2	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC3	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC4	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC5	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC6	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC3ff	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC4ff	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC5ff	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
183	PC6ff	pico bur	Diamond dental bur, reusable	45602249800002097D	MDN 1208 Non-active non-implantable instruments	L159099	Ila	rule 5, second paragraph
184	ISD900	ISD900 Cordless Prosthodontic Screwdriver With Torque Calibration System	Surgical screwdriver, reusable	45602249800002106W	MDA 0311 Active non-implantable dental devices	Z121390	Ila	rule 9, first paragraph
185	Straumann Surgical Motor Pro 2	Straumann Surgical Motor Pro 2	Dental implant system	45602249800002116Y	MDA 0311 Active non-implantable dental devices	Z121101	Ila	rule 9, first paragraph
186	SGO-KV	smartGun ONE KV complete set	Dental abrasive air jet system handpiece	456022498000021272	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph
186	SGO-SR	smartGun ONE SR complete set	Dental abrasive air jet system handpiece	456022498000021272	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph
186	SGO-HP	handpiece	Dental abrasive air jet system handpiece	456022498000021272	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph
187	SGP-KV	smartGun PERIO KV complete set	Dental abrasive air jet system handpiece	456022498000021374	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph
187	SGP-SR	smartGun PERIO SR complete set	Dental abrasive air jet system handpiece	456022498000021374	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph
187	SGP-HP	handpiece	Dental abrasive air jet system handpiece	456022498000021374	MDA 0311 Active non-implantable dental devices	Z121190	Ila	rule 9, first paragraph