Features

High quality stainless steel housing	1.
1 Three-way syringe (air/water/spray) with sterilisable tips	1.2.1.
Integrated spray water system for syringe and instruments (check valve prevents the back flow of water)	
3 instrument hoses with light (6-hole connector)	1.2.2.
Instrument hoses detachable	
Spray adjustment regulators for each instrument	1.3.
1 Saliva/Surgical suction hose including oral-dry-cup	1.2.6.
1 High-performance suction hose 300 l/min Continuously adjustable Unique BPR Swiss technology	1.2.5., 1.6.
2 Spray water tanks: 2 × 0.75 litres	1.7.
2 Suction fluid containers: 2 × 2 litres (automatic overflow protection)	1.5.
Compressed air filter regulator with hose (6 × 4 mm) for air connection	1.9.
Foot control with spray on/off function and chip	1.8.

Technical Data

Air consumption instruments: 35–55 l/min
Operating pressure handpieces: 2.5–3.5 bar
Each instrument is individually adjustable
Total weight: 22 kg
Dimensions: 535mm × 580mm × 850mm

Warranty: 2 years

Options: Electric micromotor with light including display and 30 programs, electric scaler, peristaltic pump, turbine, air motor, curing light, tray etc. 1.2.

Denta-Cart Clinic

For the flexible dentist

The DENTA-CART CLINIC combines 1 three-way-syringe, 3 treatment instruments and 2 suction devices (integrated suction machine) on one single cart!

Aside from treating your patients in your dental clinic, it offers you the flexibility to treat them in hospitals, retirement homes or other institutions. You can easily move your DENTA-CART CLINIC from one room to the next.

To activate and use your DENTA-CART CLINIC simply connect it to an air source and plug it in the power cord. The DENTA-CART CLINIC, designed and manufactured in Switzerland, in addition to flexible application, is also marked by high performance, little need to apply maintenance, and easy use. 1.9.

The high performance suction (300 l/min!) with unique BPR Swiss technology is complemented by instruments thoroughly efficient even with continuous operation. The great comfort of the DENTA-CART CLINIC is rounded of by the convenience of external removable instrument hoses and useful connections for external devices.

Savybės

Aukštos kokybės nerūdijančio plieno korpusas	*1.*
1 trijų funkcijų švirkštas (oras/vanduo/purškimas) su sterilizuojamais antgaliukais	*1.2.1.*
Integruota švaraus vandens sistema švirkštui ir instrumentams (atbulinis vožtuvas apsaugo nuo vandens patekimo atgal į vidų)	
3 instrumentų rankovės su pašvietimo funkcija (6-skylių jungtis)	*1.2.2.*
Nuimamos instrumentų rankovės	
Purškimo srovės reguliatoriai kiekvienam instrumentui atskirai	*1.3.*
1 seilių išsiurbimo žarna su puodeliu išspjauti seilėms	*1.2.6.*
1 stambių dalelių išsiurbimo žarna su 300 l/min srautu Tolygiai reguliuojama Unikali „BPR Swiss“ technologija	*1.2.5., 1.6.*
2 švaraus vandens indai: 2 x 0,75 litro	*1.7.*
2 skysčių surinkimo indai: 2 x 2 litrai (su automatine apsauga nuo perpylimo)	*1.5.*
Suspausto oro srovės reguliatorius su filtru ir žarna (6 x 4 mm) oro pajungimui	*1.9.*
Kojinis pedalas su purškimo įjungimo/išjungimo funkcija ir instrumentų prapūtimu	*1.8.*

Techniniai duomenys

Instrumentų oro sunaudojimas: 35-55 l/min.
Antgalių darbinis slėgis: 2,5 – 3,5 bar
Kiekvienas instrumentas yra atskirai reguliuojamas
Bendras svoris: 22 kg
Matmenys: 535 mm x 580 mm x 850 mm *1.1.*

Garantija: 2 metai

Papildomi įrenginiai: elektrinis mikrovariklis su pašvietimo funkcija ir panele su 30 programų, elektrinis skaleris, peristaltinis siurblys, turbininis antgalis, orinis mikrovariklis, polimerizavimo lempa, padėkliukas ir t.t. *1.2.*

Saliva suction hose

External device connection

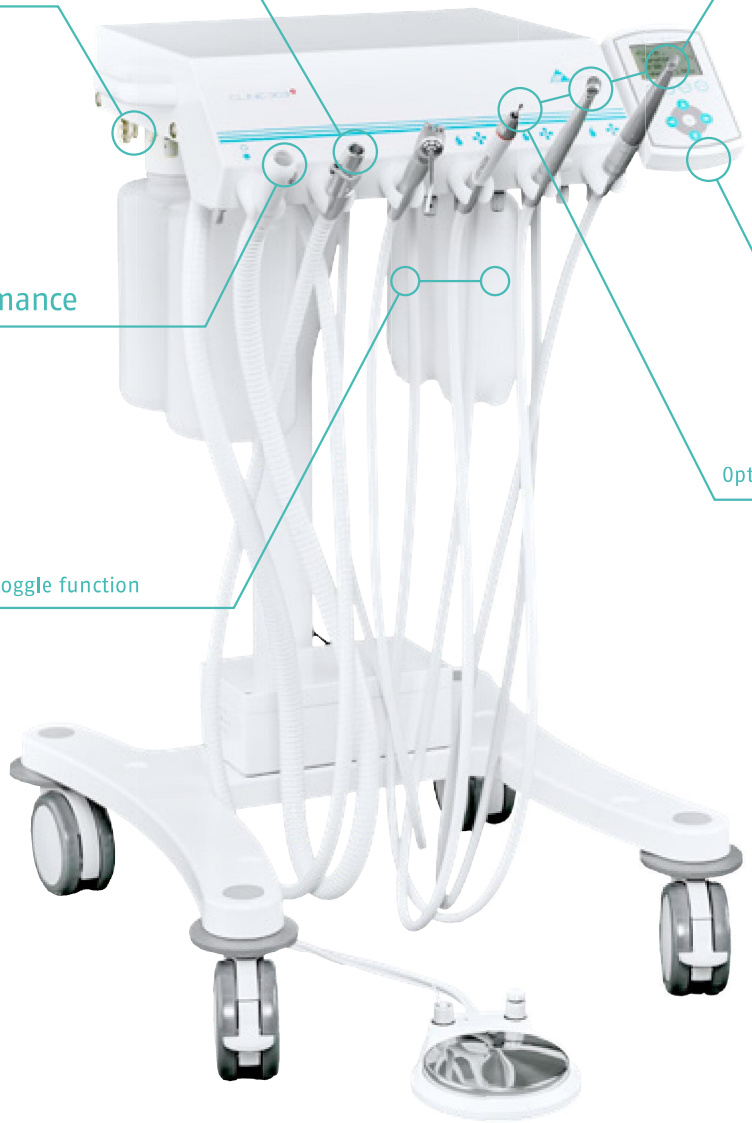
Full performance of all handpieces

Option 30 freely selectable programs
incl. 10 Endo

Self-contained high-performance
suction 300 l/min

Options Handpieces freely selectable

Two spray water tanks with toggle function



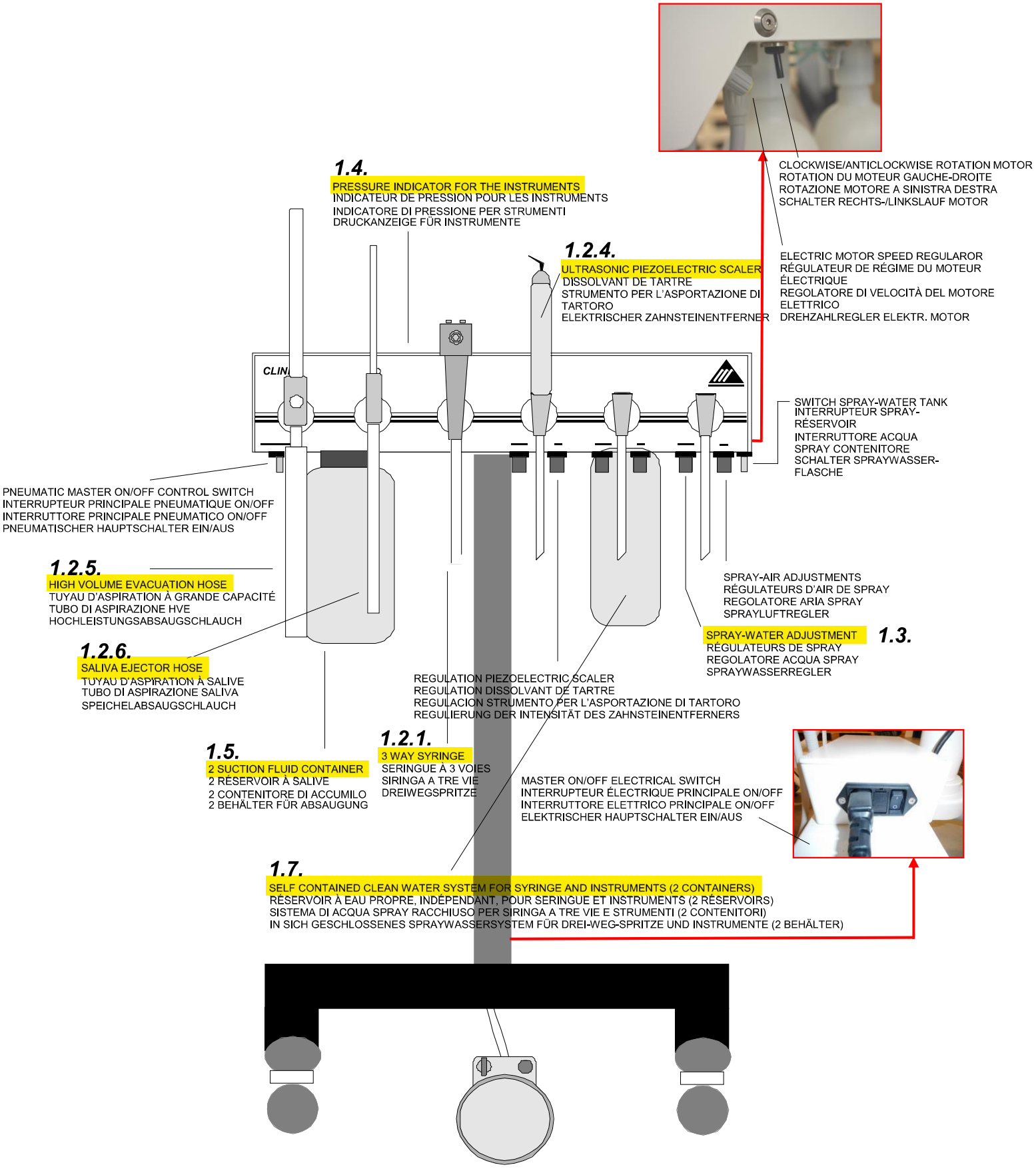
1.

Continuous Operation

Full Performance

Mobile/Rollable

8.2. Version with electrical scaler



12. Technical data

1.10.

Voltage	230 V~
Supply frequency	50/60 Hz
Requirements primary fuses	2x T6.3AH250Vac, 5x20 mm
Operating atmosphere pressure	700-1060 hPa
Weight	22 kg
Dimensions (WxDxH)	535 mm x 580 mm x 850 mm
Instrument air consumption	35 – 55 l/min
Instrument working pressure	2,5 – 3,5 bar

Climatic conditions for the storage and transport
Temperature –30°C up to +60°C
Relative air humidity 10% up to 90 %

Climatic conditions for the operation
Temperature +5°C up to 45°C
Relative air humidity up to +70%

13. Correcting malfunctions

Malfunction	Possible cause	Remedy
Device does not work	Plug is not plugged in	Plug in
Device does not work	Fuses	Check fuses and exchange if need be
Suction does not work	Waste water bottle is full	Empty waste water bottle
Spray does not work	Spray water bottles are empty	Fill spray water bottles
(Error) Messages on the display	See instruction manual of Bien-Air	See instruction manual of Bien-Air

Synea Fusion:
Synea turbines with maximum efficiency

User comfort with no compromises and top performance combined with outstanding cost-efficiency: Discover the advantages of the new Synea Fusion line!

Further advantages at a glance

- Outstanding ergonomics
- Low weight
- Especially quiet rotor
- Low-noise operation
- Ceramic ball bearings
- Hygienic head system
- Long service life
- Quality made in Austria
- Thermo washer disinfectable and sterilizable

Optimum cooling of four sides

2.1. Constant cooling and optimal cleaning of the treatment site thanks to 4x spray.

Experience LED+

Excellent illumination with natural colour rendering and optimal positioning of the LED. 2.2.

The choice is yours

Choose between the two different head sizes and then select the connection which suits your coupling system. The W&H Roto Quick offers you unbeatable LED+ light and convenient 360° rotation.

Synea Fusion:
Technical data

2.8.

Types:	TG-97 L / TG-97 L RM / TG-97 LM / TG-97 L N / TG-97	2. TG-98 L / TG-98 L RM / TG-98 LM / TG-98 L N / TG-98	
Light:	LED + / LED + / compact glass rod / compact glass rod /–	LED + / LED + / compact glass rod / compact glass rod /–	2.2.
CRI (LED version):	> 90	> 90	
Colour temperature (LED version):	5,500 K	5,500 K	
Luminous flux (lumens):	6.0 / 6.0 / 4.0** / depending on coupling / –	6.0 / 6.0 / 4.0** / depending on coupling / –	
Illuminating power:	25,000 Lux	25,000 Lux	
Coupling:	**1** Roto Quick RM-connection **2** Multiflex®*** NSK Mach®***	**1** Roto Quick RM-connection **2** Multiflex®*** NSK Mach®***	2.5.
Head size:	Ø 10 mm	Ø 11.5 mm	2.6.
Head height:	21.1 mm (with bur 19 mm)	21.4 mm (with bur 19 mm)	
Power*:	18 W	21 W	2.4.
rpm (min⁻¹):	390,000	360,000	2.3.
Rotary instruments:	FG bur, as per ISO 1797-1, with Ø 1,6 mm		
Max. operating part diameter:	2 mm	2 mm	
Max. length:	21 mm	25 mm	
Weight:	40 g / 43g / 68 g / 52 g / 40 g	42 g / 44 g / 70 g / 53 g / 42 g	
Roto Quick connection operating pressure: **Multiflex® connection operating pressure:**	3 ± 0,3 bar 2.5 to 4 bar	3 ± 0,3 bar 2.5 to 4 bar	
Spray outlets:	4x	4x	2.1.
Volume:	59 dB (A)	59 dB (A)	

* Performance value applies at a rated pressure of 3 bar and exhaust air pressure of max. 0.2 bar
** Values apply for use of RM-34 LED with DC power supply
*** Multiflex® and NSK Mach® are trademarks of third parties not affiliated with W&H Dentalwerk Bürmoos GmbH

1

W&H Roto Quick couplings enable the versatile use of instruments with Ring LED+, LED+, LED and halogen light

- Click and pull
- Continuous regulation of the spray water supply
- Clean head system
- Sterilizable
- 24-month guarantee

2

W&H RM-34 LED coupling for Multiflex®* connection**

- Use of LED without requiring changes to an optic dental unit
- Long LED service life
- Continuous regulation of the spray water supply
- Clean head system
- 24-month guarantee

„Synea Fusion“:
Techniniai duomenys

	2.	
Modelis:	**TG-98 L / TG-98 L RM / TG-98 LM / TG-98 L N / TG-98**	
Pašvietimas:	LED+ / LED+ / šviesolaidis / šviesolaidis / -	***2.2.***
Spalvų perteikimo indeksas (CRI) (LED versija):	> 90	
Spalvos temperatūra (LED versija):	5.500 K	
Šviesos srautas (lumenai):	6,0 / 6,0 / 4,0 / priklausomai nuo jungties / -	
Apšvietimo galingumas:	25.000 Lux	
Jungtis:	1) „Roto Quick“ su RM jungtimi 2) „Multiflex“ „NSK Mach“	***2.5.***
Galvutės dydis:	Ø 11,5 mm	***2.6.***
Galvutės aukštis:	21,4 mm (su 19 mm grąžtu)	
Galingumas*:	21 W	***2.4.***
Apsisukimų skaičius (aps./min.):	360.000	***2.3.***
Grąžtai:	Pagal EN ISO 1797-1:1995 FG grąžtas su Ø 1,6 mm	
Maks. darbinės dalies skersmuo:	2 mm	
Maks. ilgis:	25 mm	
Svoris:	42 g / 44 g / 70 g / 53 g / 42 g	
Greitos jungties „Roto Quick“ darbinis slėgis: Greitos jungties „Multiflex“ darbinis slėgis:	3 ± 0,3 bar Nuo 2,5 iki 4 bar	
Išpurškimo taškai:	4	***2.1.***
Triukšmingumas:	59 dB (A)	

*Galingumo parametras, kai naudojamas 3 bar slėgis ir 0,2 bar išmetamo oro slėgis.

Jungtys „W&H Roto Quick“ leidžia naudoti instrumentus su žiedu LED+, LED+, LED ir halogeniniu pašvietimu
- Lengvai uždedama ir nuimama
- Nuolatinis vandens išpurškimo reguliavimas
- Švarios galvutės sistema
- Sterilizuojama
- 24 mėnesių garantija

Jungtis su diodiniu pašvietimu „W&H RM-34“, skirta „Multiflex**“ prijungimui
- Diodinis pašvietimas be papildomų optinio odontologinio įrenginio pakeitimų
- Ilgas diodų tarnavimo laikas
- Nuolatinis vandens išpurškimo reguliavimas
- Švarios galvutės sistema
- 24 mėnesių garantija

Instructions for use

CE 0297

synea FUSION

2.

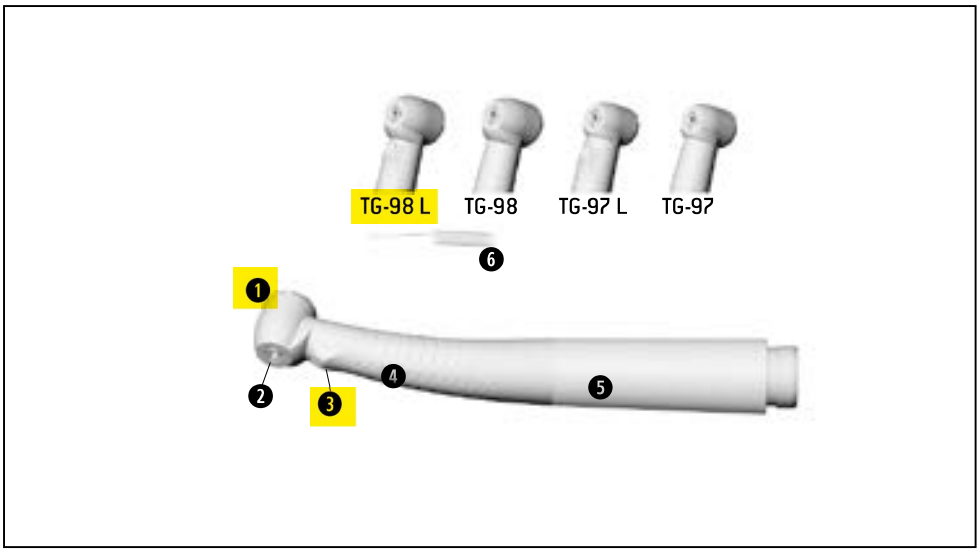
Turbine handpieces with light

TG-98 L / TG-97 L / *TG-98 LM / TG-97 LM*
TG-98 L N / TG-97 L N / TG-98 L RM / TG-97 L RM

Turbine handpieces without light

TG-98 / TG-97

3. Product description for Roto Quick coupling



1. Push-button *2.7.*
2. Spray nozzles
3. LED *2.2.*
4. Grip profile
5. Sheath
6. Nozzle cleaner

Approved sterilization procedures

Follow your country-specific directives, standards and guidelines.

> Steam sterilization class B with sterilizers in accordance with EN 13060.
> Sterilization holding time a minimum of 3 minutes at 134 °C *2.8.*

or

> Steam sterilization class S with sterilizers in accordance with EN 13060.
> The sterilizer manufacturer must give its express approval for the sterilization of turbine handpieces.
> Sterilization holding time a minimum of 3 minutes at 134 °C

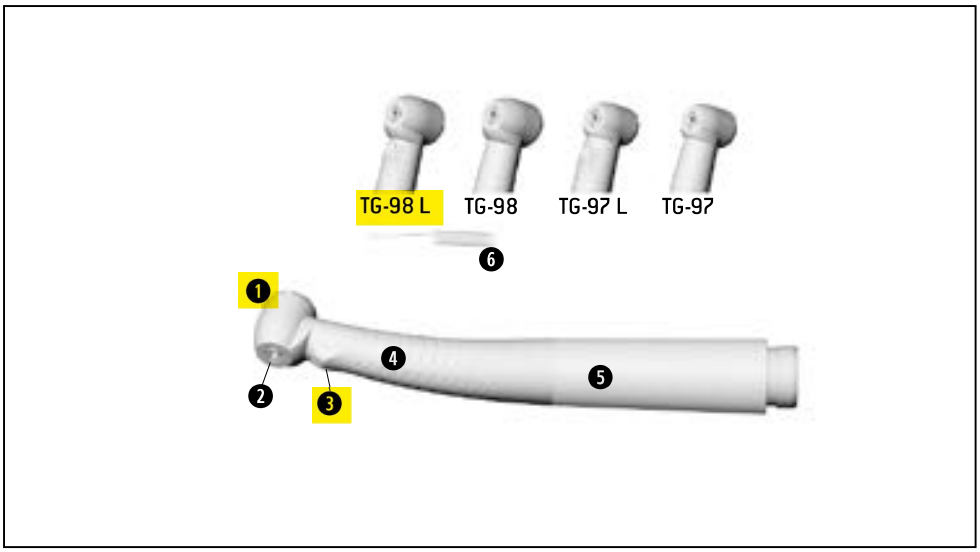
Naudojimo instrukcija

CE 0297

synea FUSION

Turbininiai antgaliai su lemputėmis
TG-98 L / TG-97 L / *TG-98 LM / TG-97 LM*
TG-98 L N / TG-97 L N / TG-98 L RM / TG-97 L RM
Turbininiai antgaliai be lemputės
TG-98 / TG-97

3. Gaminio aprašas – Roto Quick jungtis



1. Mygtukas *2.7.*
2. Purkštukai
3. Šviesos diodas *2.2.*
4. Rankenėlės profilis
4. Rankenėlės įvorė
6. Purkštuko valytuvas

12

Patvirtinti sterilizavimo metodai

Laikykitės savo šalyje galiojančių direktyvų, standartų ir nuostatų.

> B klasės sterilizavimas vandens garais sterilizatoriuose pagal EN 13060 standartą. *2.8.*
> Sterilizavimo trukmė mažiausiai 3 minutės, esant 134 °C temperatūrai

arba

> S klasės sterilizavimas vandens garais sterilizatoriuose pagal EN 13060 standartą.
> Sterilizatorių gamintojas turi būti patvirtinęs leidimą sterilizuoti turbininius antgalius.
> Sterilizavimo trukmė mažiausiai 3 minutės, esant 134 °C temperatūrai

Synea Fusion: Technical data

3.8.

			3.			
Types with light: (compact glass rod)	WG-99 LT	WG-66 LT	WG-56 LT		WG-67 LT	WG-69 LT
Types without light:	WG-99 A	WG-66 A	WG-56 A	HG-43 A	WG-67 A	WG-69 A
Head size:	Ø 10.0 mm	Ø 9.5 mm	Ø 9.5 mm 3.5.	–	–	–
Head height with bur (19 mm):	22.5 mm	20 mm	20 mm	–	–	–
Rotary instruments:	FG bur	Contra-angle handpiece bur	Contra-angle handpiece bur	Straight and contra-angle handpiece burs	Stroke 1.1 for Dentatus tips	Stroke 0.9 for Intensiv files
Max. operating part diameter:	Ø 2.5	–	–	–	defined by the available files and tips	
Max. length:	25 mm	34 mm	34 mm	34 mm		
Speed increase/reduction:	1:5	2:1	1:1 3.3.	1:1	2:1	2:1
Spray:	4x (> 50 ml/min)	1x (> 50 ml/min)	1x 3.1. (> 50 ml/min)	1x (> 50 ml/min)	1x (> 50 ml/min)	1x (> 50 ml/min)
Illuminating power in types with light:	25,000 lux	25,000 lux	25,000 lux 3.2.	–	25,000 lux	25,000 lux
Indications:	> Crown and cavity preparations > Trephining > Resections > Finishing > Removing fillings and metal	> Excavating > Preparations close to the pulp > Finishing	> Crown and cavity preparations > Trephining > Resections > Separating > Finishing of cavity margins and fillings	> Preparing > Separating > Trephining > Resections in anterior area > Minor technical procedures	> Removal of excess materials > Prepolishing > Fine polishing > Buffing in the interdental and subgingival areas > Max. rotational speed 20,000 rpm	> Finishing of interproximal and subgingival areas and cavity margins > Chamfering of the preparation edges and of cavities > Removal of sub gingival plaque > Stripping in orthodontics > Max. rotational speed 40,000 rpm

„Synea Fusion“:
Techniniai duomenys

	3.	
Modelis su pašvietimo funkcija (šviesolaidis):	**WG-56 LT**	
Modelis be pašvietimo funkcijos:	**WG-56 A**	
Galvutės dydis:	Ø 9,5 mm	***3.5.***
Galvutės aukštis (su 19 mm grąžtu):	20 mm	
Grąžtai:	Kampinių antgalių grąžtai	
Maks. darbinės dalies skersmuo:	-	
Maks. ilgis:	34 mm	
Sukimo perdavimo santykis:	1:1	***3.3.***
Išpurškimo taškai:	1 (> 50 ml/min)	***3.1.***
Apšvietimo galingumas modeliuose su pašvietimo funkcija:	25.000 Lux	***3.2.***
Indikacijos:	- Danties vainiko ir ertmės preparavimas - Trepanacija - Rezekcija - Separacija - Danties vagelių ir užpildų nugludinimas ir poliravimas	

	Model	Handpiece type	Gear ratio	Max. Speed *(rpm)*	Chuck	Light	Spray ports	Head diameter *(mm)*	Head height (mm)	Head height *(w 19 mm bur)*	Weight *(grams)*	Length *(mm)*
Synea 500 Series	WK-93LTS	compact electric high-speed	1:4.5	180,000	Push-button 1.6mm friction grip burs	yes	5	9.1	13.2	21.2	66	87
	WK-93LT	standard electric high-speed									71	96
	WK-56LTS	compact electric low-speed	1:1	40,000	Push-button 2.35mm latch burs		1	9.5	12.5	20.0	66	87
	WK-56LT	standard electric low-speed									68	96
	HK-43LT	standard electric straight			Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	88	
Synea 400 Series	WG-99LT	standard electric high-speed	1:5	200,000	Push-button 1.6mm friction grip burs	yes	4	9.5	14.5	21.7	74	96
	WG-56LT	standard electric low-speed	1:1	40,000	Push-button 2.35mm latch burs		1		13.5	21.5	68	
	WG-57LT	standard electric low-speed			Push-button 1.6mm friction grip burs			9.9	15.5	22.2	70	
	WG-66LT	standard electric low-speed	2:1	20,000	Push-button 2.35mm latch burs			9.5	13.5	21.5	68	
	HG-43A	standard electric straight	1:1	40,000	Twist-tension 2.35 mm lab burs	No	1	n/a	n/a	n/a	77	
Alegra 300 Series	WE-56T	A-dec|W&H air low-speed	1:1	20,000	Push-button 2.35mm latch burs	No	No	10.1	13.01	20.7	42	87.9
	WE-57T	A-dec|W&H air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs					22.4		
	WE-66T	A-dec|W&H air low-speed	4:1	5,000	Push-button 2.35mm latch burs					20.7		
	HE-43T	A-dec|W&H air straight	1:1	20,000	Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	44	87.1
	WE-56TMW	Midwest compatible air low-speed	1:1	20,000	Push-button 2.35mm latch burs			10.1	13.01	20.7		87.9
	WE-57TMW	Midwest compatible air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs					22.4		
	HE-43TMW	Midwest compatible air straight	1:1	20,000	Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	41	78.2
	WE-56TSD	StarDental compatible air low-speed	1:1	20,000	Push-button 2.35mm latch burs			10.1	13.01	20.7		79.7
	WE-57TSD	StarDental compatible air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs					22.4		
	HE-43TSD	StarDental compatible air straight	1:1	20,000	Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	39	66.9

3.

3.6.

3.4.

Instructions for use

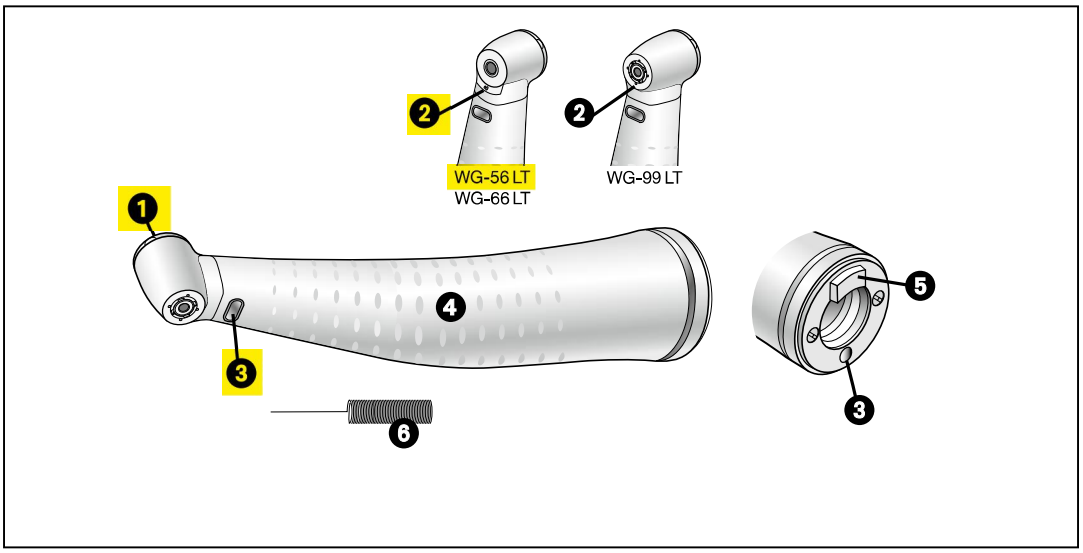
CE 0297

synea FUSION

Straight handpiece HG-43 A

Contra-angle handpieces with light
WG-99 LT, WG-56 LT, WG-66 LT

Contra-angle handpieces without light
WG-99 A, WG-56 A, WG-66 A



Contra-angles

1. Press-button *3.7.*
2. Spray nozzle *3.1.*
3. Compact optic outlet* *3.2.*
4. Grip profile
5. Nose*
6. Nozzle cleaner

* only contra-angles with light

Approved sterilization methods

Observe your country-specific guidelines, standards and requirements.

> Steam sterilization class B (pre and post vaccum) with sterilizers in accordance with EN 13060. Sterilization holding time a minimum of 3 minutes at 134 °C *3.8.*

or

> Steam sterilization class S with sterilizers in accordance with EN 13060.
The sterilizer manufacturer must give their express approval for the sterilization of handpieces/contra-angles.
Sterilization holding time a minimum of 3 minutes at 134 °C

Naudojimo instrukcija

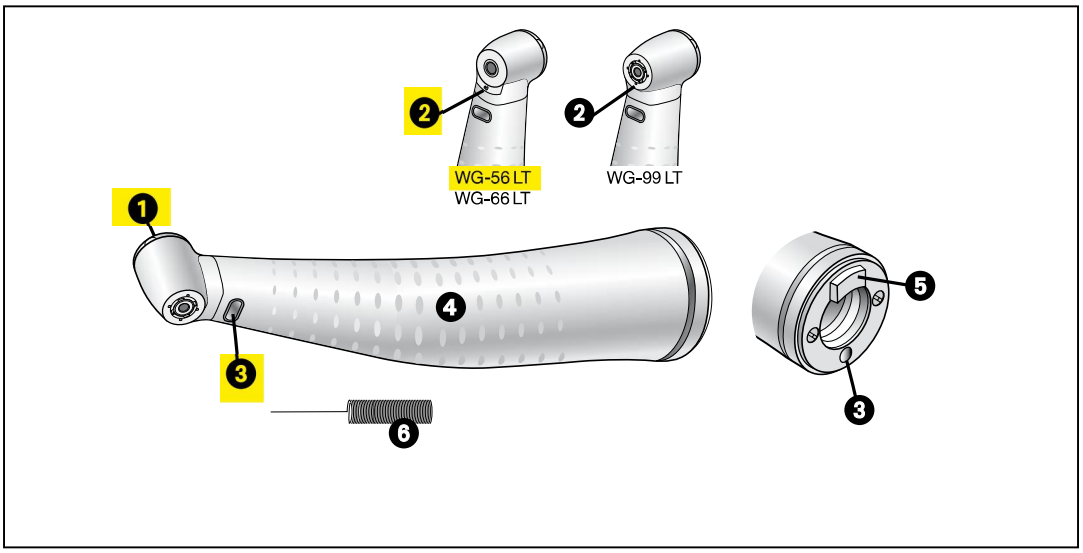
CE 0297

synea FUSION

Tiesus antgalis HE-43 A

Lenkti antgaliai su lemputėmis
WG-99 LT, WG-56 LT, WG-66 LT

Lenkti antgaliai be lempučių
WG-99 A, WG-56 A, WG-66 A



Lenkti antgaliai

❶ Mygtukas *3.7.*
❷ Purkštukai *3.1.*
❸ Kompaktiškas stiklo strypas* *3.2.*
❹ Rankenėlės profilis
❺ Atramėlė*
❻ Purkštuko valytuvas

* tik lenktuose antgaliuose su lemputėmis

11

Patvirtinti sterilizavimo metodai

Laikykitės savo šalyje galiojančių direktyvų, standartų ir nuostatų.

> B klasės sterilizavimas vandens garais sterilizatoriuose pagal EN 13060 standartą. Sterilizavimo trukmė mažiausiai 3 minutės, esant 134 °C temperatūrai *3.8.*

arba

> S klasės sterilizavimas vandens garais sterilizatoriuose pagal EN 13060 standartą. Sterilizatorių gamintojas turi būti patvirtinęs leidimą sterilizuoti tiesius ir lenktus antgalius. Sterilizavimo trukmė mažiausiai 3 minutės, esant 134 °C temperatūrai

NSK Air Motors Lineup

Air Motor for Optic Turbine Hoses

4. Ti-Max X205L

Optic MODEL X205L ORDER CODE M1013

4.4. • 360° Swivel with LED illumination • 32,000 LUX
• Titanium body with scratch-resistant DURACOAT
• Internal Water Spray • Max. 25,000 min⁻¹

4.2. 4.1. 4.5.

Air Motors for Non-Optic Turbine Hoses

DynaLED M205LG

Optic MODEL M205LG M4 ORDER CODE M1018

Optic MODEL M205LG B2 ORDER CODE M1019

• LED Air Motor with Micro Power Generator • 25,000 LUX
• Internal Water Spray • Max. 24,000 min⁻¹

S-Max M205

Non-Optic MODEL M205 ORDER CODE M1007

• Stainless Steel Body • Internal Water Spray
• Max. 25,000 min⁻¹

FX205m

Non-Optic MODEL FX205m M4 ORDER CODE M1005001

Non-Optic MODEL FX205m B2 ORDER CODE M1006001

• Stainless Steel Body • External Water Spray
• Max. 25,000 min⁻¹

FX205

Non-Optic MODEL FX205 M4 ORDER CODE M1005002

Non-Optic MODEL FX205 B2 ORDER CODE M1006002

• External Water Spray • Max. 25,000 min⁻¹

NAKANISHI INC. www.nsk-inc.com
700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
TEL : +81 (0)289-64-3380 FAX : +81 (0)289-62-5636

NSK Europe GmbH www.nsk-europe.de
Elly-Beinhorn-Strasse 8 65760 Eschborn, Germany
TEL : +49 (0)6196 77606-0 FAX : +49 (0)6196 77606-29

NSK United Kingdom Ltd www.nsk-uk.com
Office 5, Gateway1000, Arlington Business Park, Whittle Way, Stevenage, SG1 2FP, UK
TEL : +44 (0)1438 310670 FAX : +44 (0)1438 310671

NSK Dental LLC www.nskdental.com
1800 Global Parkway Hoffman Estates, IL 60192, USA
TEL : +1 888 675 1675 FAX : +1 800 838 3328

NSK Oceania Pty Ltd www.nskoceania.com.au
Unit 22, 198-222 Young St. Waterloo, Sydney, NSW 2017, Australia
TEL : +61 (0)2 8306 3000 FAX : +61 (0)2 8306 3030

NSK Middle East www.nsk-inc.com
Room 6EA-701, 7th Floor, East Wing No.6 Dubai Airport Free Zone, PO Box 54316 Dubai, UAE
TEL : +971 (0)4-204-5507 FAX : +971 (0)4-204-5508

NSK Asia Pte Ltd www.nsk-inc.com
1 Maritime Square, #09-33 HarbourFront Centre, Singapore 099253
TEL : +65-6376-5018 FAX : +65-6376-0233

REF PR-D779E Ver.1 13.00.00.00

NSK

The Air Motors

Ti-Max X205L / DynaLED M205LG / S-Max M205 / FX205

Powerful Partners®

NSK Oriniai mikrovarikliai

Oriniai mikrovarikliai, skirti turbininių antgalių rankovėms su pašvietimo funkcija

4. **Ti-Max X205L**

4.4. **Su pašvietimu** MODELIS **X205L** Užsakymo kodas **M1013** ***4.2.***

● 360° apsisukimas su LED pašvietimu ● 32.000 LUX

● Titaninis korpusas su įbrėžimams atspariu sluoksniu „DURACOAT“

● Vidinis aušinimas vandeniu ● Maksimalus apsisukimų skaičius 25000 aps./min. ***4.1.***

Air Clinical Micromotors

- value for money

4.3. ISO Type E easy to connect with all handpieces and contra-angles (NSK, KaVo®, Sirona®, W&H®, Bien-Air®)

- Midwest 4 holes and Borden 2/3 holes compatible
- Optic and non-optic
- Internal or external water spray
- Autoclavable up to135°

Ti-Max X205L

135°C

Optic Model: X205L Order Code: M1013

Specifications

Body Material	Titanium
Body Coating	DURACOAT
Max Speed	23,000 min^{-1} ± 10%

Features

360° Swivel with LED Illumination / 32,000 LUX / Non-retraction Valve

Dynal ED M205L G

NSK

Air Motor

Ti-Max X205L

X205L

OPERATION MANUAL

CE 0197 MADE IN JAPAN

OM-M0127E

5. Check before treatment

Connect the handpiece to the motor and check for motor vibration, noise and overheating. If any abnormalities are found do not use the motor and contact your Authorized NSK Dealer.

6. Forward / Reverse Rotation *4.1.*

1) Forward Rotation : Turn the FWD/REV Change Ring to “F”.(Fig. 3)
2) Reverse Rotation : Turn the FWD/REV Change Ring to “R”.(Fig. 4)
3) When the FWD/REV Change Ring is positioned at the middle of “F” and “R” , the drive air is interrupted and the motor does not rotate.(Fig. 5)

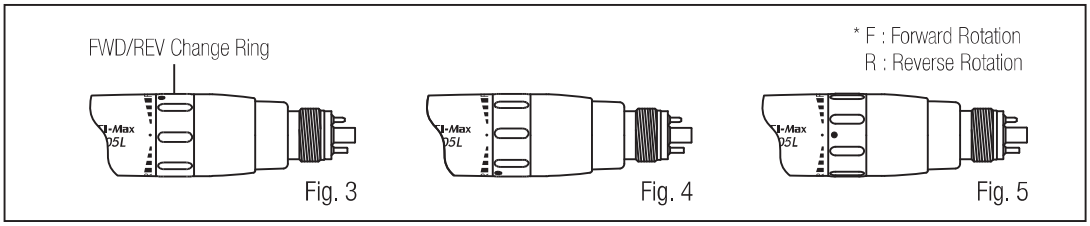


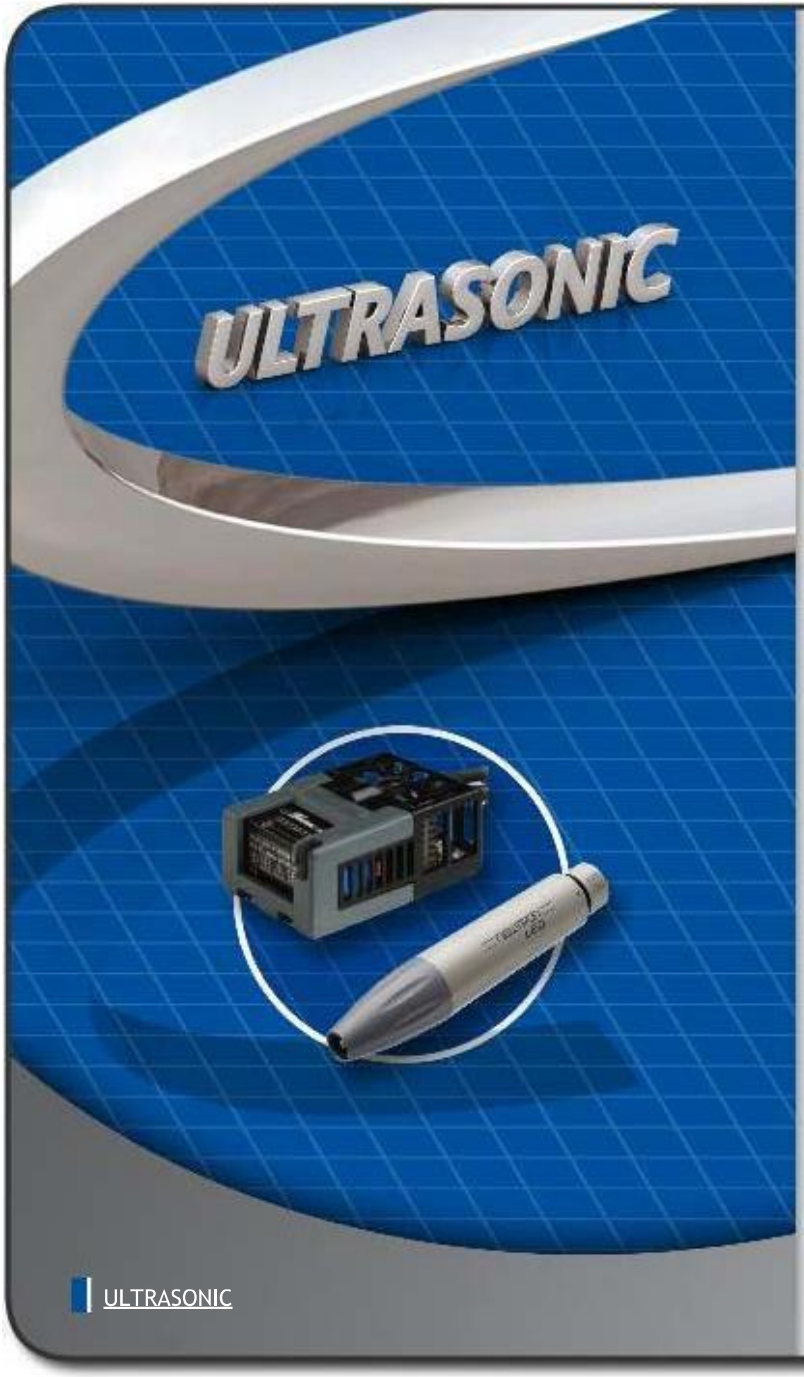
Fig. 3 Fig. 4 Fig. 5

■ Lubrication Oil
1) Remove the motor from the hose.
2) Apply 1-2 drops of lubrication oil into the Drive Air Port shown in the Fig.7.
3) Connect the motor to the hose. Operate the motor for about 10 seconds.

7-3 Sterilization

Sterilize the product by autoclave sterilization. Remove the handpiece after each patient and sterilize as noted below.

1) Insert into an autoclave pouch. Seal the pouch.
2) Autoclavable under the conditions below.
Autoclave for more than 20 min. at 121°C, or 15 min. at 132°C, or 3 min. at 134°C. *4.5.*
3) The motor should remain in the autoclave pouch until required for use.



ULTRASONIC

NEWTRON LED

The SP NEWTRON LED ® module is a multi-clinic piezo-ultrasonic unit incorporating NEWTRON® technology, compatible with the new SATELEC® Newtron LED handpiece. **5.**

The autoclavable handpiece features the latest optical and LED technologies to bring you a very reliable lighting system. **5.1.**

- Cruise Control™ technology
- LED PC board for high light intensity: 65.000 Lux
- Compatibility with the entire Satelec tip range **5.4.**
- Specific configurations upon request

Power supply	24VAC ±10% 35VA / 35VDC ±10%
Frequency	28 to 36 Khz **5.2.**
Perio	8 to 30 mA
Endo	32 to 54 mA **5.3.**
Scaling	56 to 78 mA
Boost	81 to 100 mA
Cruise Control	Yes
Control Light	Yes
Module	75 x 49 x 33 mm

SP 4055 | SP NEWTRON | NEWTRON LED
DIAGRAM | REFERENCES | ULTRASONIC INDEX
PRODUCT RANGE | COMMERCIAL CONFIGURATIONS

ACTEON • 17 av. Gustave Eiffel • BP 30216 • 33708 MERIGNAC cedex • FRANCE
Tel +33 (0) 556 34 06 07 • Fax +33 (0) 556 34 92 92 • E-mail: oem.info@acteongroup.com • www.acteongroup.com

5.

„SP NEWTRON LED“

„SP NEWTRON LED“ valdymo modulis yra daugiafunkcinis pjezo-ultragarsinis įrenginys su integruota technologija „NEWTRON“ bei suderinamas su antgaliu „SATELEC Newtron LED“.

5.1. Autoklavuojamas antgalis su naujausia diodinio LED pašvietimo technologija yra patikima apšvietimo sistema.

- Technologija „Cruise Control“
- Plokštė su LED pašvietimu: 65.000 Lux šviesos intensyvumas
- Suderinama su visu „Satelec“ instrumentų asortimentu. *5.4.*
- Galima specifinė konfigūracija pagal poreikį.

Maitinimas	24 V AC ±10% 35 W/35 V DC ±10%
Dažnis *5.2.*	Nuo 28 iki 36 kHz
Periodontinis režimas *5.3.*	Nuo 8 iki 30 mA
Endodontinis režimas	Nuo 32 iki 54 mA
Profilaktinis režimas	Nuo 56 iki 78 mA
„Boost“ režimas	Nuo 81 iki 100 mA
Automatinio sureguliavimo sistema „Cruise Control“	Yra
Pašvietimo funkcija	Yra
Modulis	75 x 49 x 33 mm

ULTRASONICS
Dental tips

5.4.

scaling

Scaling

N°1
F00246
Universal

N°2
F00247
High power

N°3
F00248
Removing stains

10P
F00253
Supra and sub-gingival < 3mm

10X
F00359
Interproximal

10Z
F00254
Subgingival

N°1S
F00245
Supra and sub-gingival

perioDontics

Curettes & debridement

H1
F00366
Anterior teeth, diamond-coated

H2L
F00367
Premolars & molars, l eft-angled

H2R
F00368
Premolars & molars, right-angled

H3
F00369
Anterior teeth, curette

H4L
F00114
Premolars & molars, left-angled

H4R
F00115
Premolars & molars, right-angled

perioFine

Periofine

PFU
F02170
Universal

PFL
F02171
Left-angled

PFR
F02172
Right-angled

Class IIa medical devices (GMED) - CE 0459

implantProtect

Pure Titanium

Peri-implantitis treatment

IP1
F02121
Implant abutments and wide threads

IP2L
F02122
Medium implant threads, left-angled

IP2R
F02123
Medium implant threads, right-angled

IP3L
F02124
Narrow implant threads, left-angled

IP3R
F02125
Narrow implant threads, right-angled

perioMaintenance

BDR

Periodontal maintenance (BDR)

TK1-1S
F01001
Short probe

TK1-1L
F01004
Long probe

TK2-1L
F02162
Premolars & molars, left-angled

TK2-1R
F02161
Premolars & molars, right-angled

perioSoft

implant maintenance

PH1 (x4)
F00702
Anterior teeth

PH2L (x4)
F00705
Premolars & molars, left-angled

PH2R (x4)
F00706
Premolars & molars, right-angled

perioPrecision

PerioPrecision

P2L
F00090
Narrow pockets debridement, left-angled

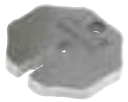
P2R
F00091
Narrow pockets debridement, right-angled

Class IIa medical devices (GMED) - CE 0459

WRENCHES

Newtron® wrench *F81322*
autoclavable and dynamometric

IMPORTANT
The Newtron® wrench is used with surgical endodontics tips: AS3D, AS6D, AS9D, ASLD, ASRD, S12-70D, P14D, P15LD et P15RD.
For other tips with yellow ring, the universal wrench (Ref. F00406) is recommended.



5.4.
Universal wrench *F00406*

Protec-Tip *F81281*

BOXES

Autoclavable plastic box
+ 4 autoclavable dynamometric
Newtron® wrenches *F12352*

Autoclavable plastic box *F12351*
for autoclavable dynamometric wrenches

SUPPORTS

Newtron® kit support *X88451*

Endo Success™ kit support *F88447*

Perfect Margin® kit support *F88448*

Excavus® kit support *F88449*

EC-Certificate

SQS as a conformity assessment body identification number 1250 herewith certifies the company

BPR Swiss GmbH
Weststrasse 16
3672 Oberdiessbach
Switzerland

the use of a quality assurance system in its manufacturing and distribution which fulfills the requirements set out in:

ANNEX V

Directive 93/42/EEC

This approval is based on the result of the report dated January 28, 2019.

The scope of validity covers the products

Portable and mobile dental operatory units

The following CE label can be applied to these products mentioned in this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex V.4 of the Directive 93/42/EEC

Validity 01.03.2019–28.02.2024
Issue 01.03.2019

Reg. no. 43311
Approved PV Medical 11.02.2019

F. Müller, CEO SQS

D. Taddeo, Medical Responsible

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Partner of IQNet

sqs.ch

4174_2//May 2018/Version 1.0

Declaration of Conformity
CE-Erklärung
Declaración de Conformidad

We / Wir / Nosotros

W&H DENTALWERK BÜRMOOS GmbH
Ignaz-Glaser-Straße 53
A-5111 Bürmoos / Österreich

declare under our sole responsibility that the products
erklären in alleiniger Verantwortung, dass die Produkte
declaramos bajo nuestra total responsabilidad que nuestros productos

Turbines / Turbinen / Turbinas

(According to page 2 / gemäß Seite 2 / Conforme al Pagina 2)

to which this declaration relates, fulfil the requirements **of the Directives 93/42/EEC** (Medical Devices), 2006/42/EC (Machinery) and 2011/65/EU (RoHS)*.

auf die sich diese Erklärung bezieht, den Anforderungen **der Richtlinien 93/42/EWG** (Medizinprodukte), 2006/42/EG (Maschinen) und 2011/65/EU (RoHS)* entsprechen.

a los que esta declaración afecta, corresponden a las exigencias de las **Directivas 93/42/CEE** (Productos Sanitarios), 2006/42/CE (Máquinas) y 2011/65/EU (RoHS)*.

Class / Klasse / clase: **IIa** Rule / Regel / regla: **9**

Conformity assessment procedure / Konformitätsbewertungsverfahren / Evaluación de la conformidad:

Annex / Anhang / Anexo: II

Notified Body / Benannte Stelle / Organismo Certificador: **DQS Medizinprodukte GmbH**
August-Schanz-Straße 21
D-60433 Frankfurt/Main

Identification no. / Kennnummer / Identificatión N°: **0297**

Certificate unique ID: 170661091
Certificate product group: Turbine handpieces and adapters

*RoHS: without involvement of the notified body / ohne Einbezug des Notified Body / sin la participación del organismo certificador

Expiry date / gültig bis / valido hasta: 09.08.2020

Significant changes to the medical devices provoke the loss of validity.
Bei signifikanten Änderungen der Produkte verliert die CE-Erklärung ihre Gültigkeit.
En caso de modificaciones significantes de los productos la Declaración de Conformidad pierde la validez.

Bürmoos, 28.10.2016

.....
Ing. Wolfgang Stadler
Product responsibility/Project sponsor
Produktverantwortlicher/Projektauftraggeber
Persona responsable del producto/Cliente del proyecto

Description / Bezeichnung / Descripción	*Type/Tipo*	*REF*	*SN* (from/ab/desde)
Synea Turbine / Turbine / Turbina	TA-97 C LED	***10069705***	***107792***
Synea Turbine / Turbine / Turbina	TA-97 C	***10069706***	***100920***
Synea Turbine / Turbine / Turbina	TA-97 CLM	***10069715***	***100955***
Synea Turbine / Turbine / Turbina	TA-98 C LED	***10069805***	***118607***
Synea Turbine / Turbine / Turbina	TA-98 C	***10069806***	***102678***
Synea Turbine / Turbine / Turbina	TA-98 CLM	***10069815***	***103345***
Synea Turbine / Turbine / Turbina	TG-98 L	***30001***	***001001***
Synea Turbine / Turbine / Turbina	TG-98	***30002***	***001001***
Synea Turbine / Turbine / Turbina	TG-98 LM	***30003***	***001001***
Synea Turbine / Turbine / Turbina	TG-97 L	***30004***	***001001***
Synea Turbine / Turbine / Turbina	TG-97	***30005***	***001001***
Synea Turbine / Turbine / Turbina	TG-97 LM	***30006***	***001001***
Synea Turbine / Turbine / Turbina	TK-94 L	***30016***	***01001***
Synea Turbine / Turbine / Turbina	TK-97 L	***30017***	***01001***
Synea Turbine / Turbine / Turbina	TK-97 LM	***30018***	***01001***
Synea Turbine / Turbine / Turbina	TK-98 L	***30019***	***01001***
Synea Turbine / Turbine / Turbina	TK-98 LM	***30020***	***01001***
Synea Turbine / Turbine / Turbina	TK-100 L	***30021***	***01001***
Synea Turbine / Turbine / Turbina	TK-100 LM	***30022***	***01001***
Synea Turbine / Turbine / Turbina	TK-94 LM	***30031***	***01001***
Synea Turbine / Turbine / Turbina	TG-97 L RM	***30197***	***00801***
Synea Turbine / Turbine / Turbina	TG-98 L RM	***30198***	***00801***
Synea Turbine / Turbine / Turbina	TG-97 L N	***30199***	***00801***
Synea Turbine / Turbine / Turbina	TG-98 L N	***30200***	***00801***

Vertimas iš anglų kalbos

/logotipas: PEOPLE HAVE PRIORITY W&H/

EB Atitikties deklaracija

Mes

W&H DENTALWERK BÜRMOOS GmbH
Ignaz-Glaser-Straße 53
A-5111 Bürmoos / Austrija

Su visa atsakomybe pareiškiame, kad gaminiai

Turbininiai antgaliai

(pagal 2 lapą)

kuriems taikoma ši deklaracija, atitinka **Direktyvos 93/42/EEB** (Medicinos prietaisai), 2006/42/EB (Mašinos) ir 2011/65/ES (RoHS)* nuostatas.

Klasifikacija: **IIa Klasė** Taisyklė: **9 Taisyklė**

Atitikties įvertinimo procedūra buvo atlikta pagal:

II Priedą.

Notifikavimo įstaiga: **DQS Medizinprodukte GmbH**
August-Schanz-Straße 21
D-60433 Frankfurtas prie Maino
Identifikavimo Nr.: **0297**

Sertifikato registravimo Nr.: 170661091
Sertifikato gaminių grupė: Turbininiai antgaliai ir adapteriai

*RoHS: notifikavimo įstaigai nedalyvaujant.

Galiojimo data: 2020-08-09.

Reikšmingi prietaisų pakeitimai sąlygoja deklaracijos galiojimo nutraukimą.

2016-10-28, Bürmoos

/parašas/

Inž. Wolfgang Stadler
Atsakingas už gaminį/projekto autorius

Aprašymas	*Tipas*	*Užsakymo numeris*	*Serijos numeris (nuo)*
Turbininis antgalis „Synea“	**TA-97 C LED**	***10069705***	***107792***
Turbininis antgalis „Synea“	**TA-97 C**	***10069706***	***100920***
Turbininis antgalis „Synea“	**TA-97 CLM**	***10069715***	***100955***
Turbininis antgalis „Synea“	**TA-98 C LED**	***10069805***	***118607***
Turbininis antgalis „Synea“	**TA-98 C**	***10069806***	***202687***
Turbininis antgalis „Synea“	**TA-98 CLM**	***10069815***	***103345***
Turbininis antgalis „Synea“	**TG-98 L**	***30001***	***001001***
Turbininis antgalis „Synea“	**TG-98**	***30002***	***001001***
Turbininis antgalis „Synea“	**TG-98 LM**	***30003***	***001001***
Turbininis antgalis „Synea“	**TG-97 L**	***30004***	***001001***
Turbininis antgalis „Synea“	**TG-97**	***30005***	***001001***
Turbininis antgalis „Synea“	**TG-97 LM**	***30006***	***001001***
Turbininis antgalis „Synea“	**TK-94 L**	***30016***	***01001***
Turbininis antgalis „Synea“	**TK-97 L**	***30017***	***01001***
Turbininis antgalis „Synea“	**TK-97 LM**	***30018***	***01001***
Turbininis antgalis „Synea“	**TK-98 L**	***30019***	***01001***
Turbininis antgalis „Synea“	**TK-98 LM**	***30020***	***01001***
Turbininis antgalis „Synea“	**TK-100 L**	***30021***	***01001***
Turbininis antgalis „Synea“	**TK-100 LM**	***30022***	***01001***
Turbininis antgalis „Synea“	**TK-94 LM**	***30031***	***01001***
Turbininis antgalis „Synea“	**TG-97 L RM**	***30197***	***00801***
Turbininis antgalis „Synea“	**TG-98 L RM**	***30198***	***00801***
Turbininis antgalis „Synea“	**TG-97 L N**	***30199***	***00801***
Turbininis antgalis „Synea“	**TG-98 L N**	***30200***	***00801***

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60118708 0001

Report No.: 12031343 001

Manufacturer:
Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan

Products:
Instruments and Equipment in Dental and Surgical Fields

(see attachments for products included)

Replaces Approval, Registration No.: HD 60099567 0001

Expiry Date: 2022-05-08

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-02-26

Date: 2018-02-26

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60118708 0001
Report No.: 12031343 001

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan

Products included:

- Pneumatic dental drilling system handpiece
- Diamond dental bur, reusable
- Dental drilling system attachment
- Line-powered dental drilling system handpiece
- Pneumatic dental scaling system handpiece
- Pneumatic dental scaling system handpiece tip
- Air Motor
- Remotely-driven dental drilling system motor
- Endodontic enlarger
- Dental-professional prophylaxis motor
- Endodontic apex locator
- Dental abrasive air jet system handpiece
- Dental abrasive powder
- Sawing power tool attachment, reciprocating
- Sawing power tool attachment, oscillating

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2018-02-26

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60118708 0001
Report No.: 12031343 001

Manufacturer:
Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan

Products included:

- Sawing power tool attachment, sagittal
- Reciprocating surgical saw blade, reusable
- Oscillating surgical saw blade, reusable
- Sagittal surgical saw blade, reusable
- Dental implant system
- Surgical screwdriver, reusable
- Ultrasonic dental scaling system
- Ultrasonic dental scaling system handpiece tip
- Dental ultrasonic surgical system handpiece tip
- Dental ultrasonic surgical system
- Total Surgical System
- Sterile Products:
  - Sterile Drills
  - Sterile Burs
  - Sterile Blades
  - Sterile Rasps
  - Sterile Files
- Dental suction system, non-surgical

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2018-02-26

M.Sc. M. Aihara

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60118708 0001
Report No.: 12031343 001

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan

Products included:

- Pneumatic Surgical Drilling Machine
- Electric drill system for dental surgery, dental implant surgery and foot- and ankle- surgery
- External Coolant Straight Handpiece for foot surgery and oral surgery

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2018-02-26

M.Sc. M. Aihara

令和元年登簿第　398　号

認　　証

嘱託人株式会社ナカニシ鈴木みどりの提出した別添証書の謄本は、その原本と対照し、原本と符合することを認めた。

よって、これを認証する。

令和元年　6　月　7　日、本公証人役場において

東京都台東区東上野１丁目７番２号

東　京　法　務　局　所　属

公　証　人

Notary

津留寅雄

TORAO　TSUKUMA

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和元年　6　月　7　日

東　京　法　務　局　長　　岩　山　伸　二

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country:　JAPAN
   This public document
2. has been signed by　TORAO　TSUKUMA
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of　TORAO TSUKUMA, Notary
   Certified
5. at Tokyo　　6. JUN. 07. 2019
7. by the Ministry of Foreign Affairs
8. 19-№051137
9. Seal/stamp:　　10. Signature

MINISTRY OF FOREIGN AFFAIRS · JAPAN

T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs

ATITIKTIES PATVIRTINIMAS

ES Direktyvos 93/42/EEB II Priedas, išskyrus 4 Straipsnį
Pilna Kokybės Užtikrinimo sistema
Medicinos prietaisai

Registracijos Nr.: HD 60118708 0001

Protokolo Nr. 12031343 001

Gamintojas: **Nakanishi Inc.**
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Taikymo sritis: Odontologinių ir chirurginių instrumentų bei įrenginių sritys (dizainas, vystymas ir gamyba)

(žiūrėti pridėtą produktų sąrašą)

Atitikties patvirtinimo, registracijos Nr.: HD 60099567 0001, pakeitimas

Galiojimo laikas: 2022-05-08

Šiuo Notifikavimo įstaiga patvirtina, kad ES Direktyvos 93/42/EEB Priedo II reikalavimai, išskyrus 4 skyrių, buvo išpildyti išvardintiems produktams. Aukščiau minėtas gamintojas turi įdiegtą ir vykdomą kokybės vadybos sistemą, kuri yra periodiškai stebima, kaip nustatyta II Priedo 5 straipsnyje. Pardavimui rinkoje III klasės įrenginių apimamų šio sertifikato, yra reilakingas ES projektavomo-patikrinimo sertifikatas pagal II Priedą 4 skyrių.

Notifikavimo įstaiga

Įsigaliojimo data: **2018-02-26**

Data: **2018-02-26**

Dipl. Inž. M. Aihara

„TÜV Rheinland LGA Products GmbH“ – Tillystraße 2 – 90431 Niurnbergas

TÜV Rheinland LGA Products GmbH yra notifikuojanti įstaiga pagal Direktyvą 93/42/EEB medicinos įrenginiams su identifikavimo numeriu 0197

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: Nakanishi Inc.
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Oriniai odontologiniai gręžimo sistemų antgaliai
- Daugkartinio naudojimo deimantiniai odontologiniai grąžtai
- Odontologinių gręžimo sistemų prijungimai
- Linijimio maitinimo odontologiniai gręžimų sistemų antgaliai
- Oriniai odontologiniai skaleriai
- Orinių odontologinių skalerių antgaliukai
- Oriniai varikliai
- Nuotoliniu būdu varomi odontologiniai gręžimo sistemų varikliai
- Endodontiniai didintuvai
- Odontologiniai profilaktiniai varikliai
- Endodontinis apekso lokatorius
- Odontologiniai abrazyvios oro srovės sistemos antgaliai
- Odontologiniai abrazyvūs milteliai
- Pjaunantys galios instumentų prijungimai, darantys slankiojamąjį judesį
- Pjaunantys galios instumentų prijungimai, vibruojantys

Notifikavimo įstaiga

Data 2018-02-26

Dipl. Inž. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: **Nakanishi Inc.**
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Pjaunantys galios instumentų prijungimai, strėliniai
- Slekamojo judesio chirurginių pjūklo ašmenys, daugkartinio naudojimo
- Vibruojančių chirurginių pjūklų ašmenys, daugkartinio naudojimo
- Stėliniai chirurginiai pjovimo ašmenys, daugkartinio naudojimo
- Odontologinės implantavimo sistemos
- Chirurginiai varžtų suktuvai, daugkartinio naudojimo
- Ultragarsinių odontologinių skalerių sistemos
- Ultragarsinių odontologinių skalerių sistemų antgaliukai
- Odontologiniai ultragsinių chirurginių sistemų antgaliukai
- Odontologinės ultragarsinės chirurginės sistemos
- Bendra chirurginė sistema
- Sterilūs produktai:
  - Sterilūs grąžtai
  - Sterilūs turbininiai grąžtai
  - Sterilūs ašmenys
  - Sterilūs brūžikliai
  - Sterilios adatos
- Odontologinės atsiurbimo sistemos, ne chirurginės

Notifikavimo įstaiga

Data **2018-02-26**

Dipl. Inž. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: **Nakanishi Inc.**
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Orinės chirurginės gręžimo mašinos
- Elektrinės gręžimo sistemos odontologinei chirurgijai, odontoloiginei implantų chirurgijai bei kojos ir alkūnės chirurgijai
- Išorinio aušinimo tiesus antgalis kojos chirurgijai ir burnos chirurgijai

Notifikavimo įstaiga

Data **2018-02-26**

Dipl. Inž. M. Aihara

DECLARATION OF CONFORMITY

No. DC-1-03N-45-GR-1

MANUFACTURER

NAKANISHI INC.
700 Shimohinata, Kanuma-shi, Tochigi-ken 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8
65760 Eschborn
Germany

MEDICAL DEVICE

Dental Engines
-Air Motors

Model No.: X205L
Product name : Ti-Max X205L

Classification : Class Ⅱa (Rule 9)

NAKANISHI INC. is exclusively responsible for the declaration of conformity.

The serial number applied to this product is managed by the "Shipping history data".

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in Annex Ⅰ of EC Directive 93/42/EEC.
The declaration of conformity is based in the EC Directive 93/42/EEC Annex Ⅱ and Supported by the TÜV Rheinland LGA Products GmbH, Tillystrasse 2, 90431 Nürnberg (0197) Annex Ⅱ certificate, with reference to articles 1 and 3 of directive 93/42/EEC.

Certificate Registration No: HD 60039342 0001

And, this declaration of conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: Jun 17, 2013

Yoshihiro Kanno, Quality Assurance Dept. Manager

NSK

ATITIKTIES DEKLARACIJA

Nr. DC-1-03N-45-GR-1

GAMINTOJAS

NAKANISHI INC.
700 Shimohinata, Kanuma-shi, Tochigi-ken 322-8666, Japonija

ĮGALIOTASIS ATSTOVAS ES

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8
65760 Eschborn
Vokietija

MEDICININIS ĮRENGINYS

Odontologiniai varikliai
Oriniai varikliai

Modelio pavadinimas:	X205L
Gaminio pavadinimas:	Ti-Max X205L
Klasifikavimas:	Klasė IIa (9 taisyklė)

NAKANISHI INC. yra išskirtinai atsakinga už Atitikties deklaraciją.

Ant gaminio nurodomas serijos numeris yra fiksuojamas išsiuntimo duomenų registre.

Žemiau pasirašęs patvirtina, kad medicininos prietaisas, nurodytas aukščiau, atitinka esminius reikalavimus, nurodytus EB Direktyvos 93/42/EEB I Priede.
Atitikties deklaracija grindžiama EB Direktyvos 93/42/EEB II Priedu ir paremiama „TÜV Rheinland LGA Products GmbH“, Tillystrasse 2, 90431 Niurnbergas (0197), sertifikato II Priedu su nuoroda į 93/42/EEB direktyvos 1 ir 3 straipsnius.

Sertifikato registravimo Nr.: HD 60039342 0001

Taip pat ši Atitikties deklaracija apima EB Direktyvą 2006/42/EB.

Tochigi, Japonija: 2013 m. birželio mėn. 17 d.

Yoshihiro Kanno, Kokybės Užtikrinimo skyriaus vadybininkas

Declaration of Conformity
CE-Erklärung
Declaración de Conformidad

We / Wir / Nosotros **W&H DENTALWERK BÜRMOOS GmbH**
Ignaz-Glaser-Straße 53
A-5111 Bürmoos / Österreich

declare under our sole responsibility that the products
erklären in alleiniger Verantwortung, dass die Produkte
declaramos bajo nuestra total responsabilidad que nuestros productos

Handpieces and contra-angles / Handstücke und Winkelstücke / *Pieza de mano y contra-àngulo*
(According to page 2 / gemäß Seite 2 / Conforme al pagina 2)

to which this declaration relates, fulfil the requirements **of the Directives 93/42/EEC** (Medical Devices), 2006/42/EC (Machinery) and 2011/65/EU (RoHS)*.

auf die sich diese Erklärung bezieht, den Anforderungen **der Richtlinien 93/42/EWG** (Medizinprodukte), 2006/42/EG (Maschinen) und 2011/65/EU (RoHS)* entsprechen.

a los que esta declaración afecta, corresponden a las exigencias de las **Directivas 93/42/CEE** (Productos Sanitarios), 2006/42/CE (Máquinas) y 2011/65/EU (RoHS)*.

Class / Klasse / Clase II a **Rule / Regel / regla: 9**

Conformity assessment procedure / Konformitätsbewertungsverfahren / Evaluación de la conformidad:

Annex / Anhang / Anexo: II

Notified Body / Benannte Stelle / Organismo Certificador: **DQS Medizinprodukte GmbH**
August-Schanz-Straße 21
D-60433 Frankfurt/Main

Identification no. / Kennnummer / Identificatión Nº: **0297**

Certificate unique ID: 170661091
Certificate product group: Straight and contra-angle handpieces, dental

*RoHS: without involvement of the notified body / ohne Einbezug des Notified Body / sin la participación del organismo certificador

Expiry date / gültig bis / valido hasta: 09.08.2020

Significant changes to the medical devices provoke the loss of validity.
Bei signifikanten Änderungen der Produkte verliert die CE-Erklärung ihre Gültigkeit.
En caso de modificaciones significantes de los productos la Declaración de Conformidad pierde la validez.

Bürmoos, 11.05.2017

.....

Johann Fersterer
Product responsibility/Project sponsor
Produktverantwortlicher/Projektauftraggeber
Persona responsable del producto/Cliente del proyecto

Description / Bezeichnung / Descripción	Type/Tipo	REF	SN (from/ab/desde)
Contra-angle / Winkelstück / Contra-àngulo	WG-99 LT	30007	007802
Contra-angle / Winkelstück / Contra-àngulo	WG-99 A	30008	001819
Contra-angle / Winkelstück / Contra-àngulo	WG-56 LT	30009	014634
Contra-angle / Winkelstück / Contra-àngulo	WG-56 A	30010	002462
Contra-angle / Winkelstück / Contra-àngulo	WG-66 LT	30011	002967
Contra-angle / Winkelstück / Contra-àngulo	WG-66 A	30012	001186
Contra-angle / Winkelstück / Contra-àngulo	WK-99 LT	30023	00801
Contra-angle / Winkelstück / Contra-àngulo	WK-93 LT	30024	00801
Contra-angle / Winkelstück / Contra-àngulo	WK-56 LT	30025	04014
Contra-angle / Winkelstück / Contra-àngulo	WK-66 LT	30026	01907
Contra-angle / Winkelstück / Contra-àngulo	WK-86 LT	30027	01491
Contra-angle / Winkelstück / Contra-àngulo	WG-99 LT	30195	00801
Contra-angle / Winkelstück / Contra-àngulo	WG-99 A	30196	00801
Contra-angle / Winkelstück / Contra-àngulo	WG-57 LT	30212	001182
Contra-angle / Winkelstück / Contra-àngulo	WK-99 LT S	30215	00801
Contra-angle / Winkelstück / Contra-àngulo	WK-93 LT S	30216	00801
Contra-angle / Winkelstück / Contra-àngulo	WK-56 LT S	30217	00801
Contra-angle / Winkelstück / Contra-àngulo	WK-66 LT S	30218	00801
Handpiece / Handstück / Pieza de mano	HG-43 A	30013	000801
Handpiece / Handstück / Pieza de mano	HK-43 LT	30028	00801

Vertimas iš anglų kalbos

/logotipas: PEOPLE HAVE PRIORITY W&H/

EB Atitikties deklaracija

Mes

W&H DENTALWERK BÜRMOOS GmbH
Ignaz-Glaser-Straße 53
A-5111 Bürmoos / Austrija

Su visa atsakomybe pareiškiame, kad gaminiai

Antgaliai ir kampiniai antgaliai

(pagal 2 lapą)

kuriems taikoma ši deklaracija, atitinka **Direktyvos 93/42/EEB** (Medicinos prietaisai), 2006/42/EB (Mašinos) ir 2011/65/ES (RoHS)* nuostatas.

Klasifikacija: **IIa Klasė** Taisyklė: **9 Taisyklė**

Atitikties įvertinimo procedūra buvo atlikta pagal:

II Priedą.

Notifikavimo įstaiga: **DQS Medizinprodukte GmbH**
August Schanz g. 21
D-60433 Frankfurtas prie Maino
Identifikavimo Nr.: **0297**

Unikalus sertifikato Nr.: 170661091
Sertifikato gaminių grupė: Odontologiniai tiesūs ir kampiniai antgaliai

*RoHS: notifikavimo įstaigai nedalyvaujant.

Galiojimo data: 2020-08-09

Reikšmingi prietaisų pakeitimai sąlygoja deklaracijos galiojimo nutraukimą.

2017-05-11, Bürmoos

/parašas/

Johann Fersterer
Atsakingas už gaminį/projekto autorius

Aprašymas	*Modelis*	*Užsakymo numeris*	*Serijos numeris* (nuo)
Kampinis antgalis	*WG-99 LT*	*30007*	*007802*
Kampinis antgalis	*WG-99 A*	*30008*	*001819*
Kampinis antgalis	*WG-56 LT*	*30009*	*014634*
Kampinis antgalis	*WG-56 A*	*30010*	*002462*
Kampinis antgalis	*WG-66 LT*	*30011*	*002967*
Kampinis antgalis	*WG-66 A*	*30012*	*001186*
Kampinis antgalis	*WK-99 LT*	*30023*	*00801*
Kampinis antgalis	*WK-93 LT*	*30024*	*00801*
Kampinis antgalis	*WK-56 LT*	*30025*	*04014*
Kampinis antgalis	*WK-66 LT*	*30026*	*01907*
Kampinis antgalis	*WK-86 LT*	*30027*	*01491*
Kampinis antgalis	*WG-99 LT*	*30195*	*00801*
Kampinis antgalis	*WG-99 A*	*30196*	*00801*
Kampinis antgalis	*WK-57 LT*	*30212*	*001182*
Kampinis antgalis	*WK-99 LT S*	*30215*	*00801*
Kampinis antgalis	*WK-93 LT S*	*30216*	*00801*
Kampinis antgalis	*WK-56 LT S*	*30217*	*00801*
Kampinis antgalis	*WK-66 LT S*	*30218*	*00801*
Antgalis	*HG-43 A*	*30013*	*000801*
Antgalis	*HK-43 LT*	*30028*	*00801*

LNE
Le progrès, une passion à partager

ATTESTATION/ *CERTIFICATE* **N° 21427 rev. 7**
Délivrée à Paris le 10 juillet 2017
Issued in Paris on July 10th, 2017

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité / *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificate CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

SATELEC
A Company of ACTEON Group
17 av. Gustave Eiffel
BP 30216
33708 MERIGNAC Cedex
FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux et dispositifs électro médicaux pour l'art dentaire, l'électro chirurgie et les équipements de chirurgie des os et substituts osseux, avec leurs accessoires stériles et non stériles

Medical devices and electromedical devices for dental art, electrosurgery and bone and bone substitute surgery equipments, with associated sterile and non-sterile accessories

Voir details sur addendum / *See attachment for additional information*

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159650-1, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P159650-1, the quality system - for design, manufacturing, and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une verification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date :* **July 28th, 2017 (included)**
Valable jusqu'au / *Expiry date :* **July 27th, 2020 (included)**

Laboratoire national de métrologie et d'essais • LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

GMED_D2p3RS-V3-01-2013

LNE – 21427 rev. 7
Modifie le certificat 21427-6

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Code NBOG *NBOG code*	Classe du DM *MD class*
Consoles de commande (ultrasonique, d'aéropolissage et / ou moteur) avec leurs accessoires stériles et non stériles destinées à l'art dentaire (soins conventionnels et/ou de chirurgie intra-orale) *Control consoles (ultrasonic, air polishing and / or motor) with associated sterile and non-sterile accessories for dentistry (conventional and/or intraoral surgery)*			
SUPRASSON P5 BOOSTER	AA10-05	MD 1106	IIa
P5 NEWTRON	AF48	MD 1106	IIa
P5 NEWTRON LED	AF015	MD 1106	IIa
P5 NEWTRON XS	AF52	MD 1106	IIa
P5 NEWTRON XS LED	AF016	MD 1106	IIa
NEWTRON BOOSTER	PBAB	MD 1106	IIa
NEWTRON P5 NEWTRON P5 B.LED	PBAC	MD 1106	IIa
NEWTRON P5 XS B.LED NEWTRON P5 XS B.LED BLUETOOTH	PBAD	MD 1106	IIa
VDW.ULTRA Standalone Ultrasonic	AF50-01	MD 1106	IIa
P5 PRO Ultra Piezo Ultrasonic	AF50-02	MD 1106	IIa
PROPHYMAX	AC21	MD 1106	IIa
AIR MAX	AC20	MD 1106	IIa
GENIUS	PO69	MD 1106	IIa
PIEZOTOME SOLO PIEZOTOME SOLO LED	PO23	MD 1106	IIa
PIEZOTOME 2	BE009	MD 1106	IIa
IMPLANTCENTER 2	PO24	MD 1106	IIa
PIEZOTOME CUBE	PO37	MD 1106	IIa
Modules de commande (ultrasonique, moteur) destinés à être intégrés dans un système électronique de soins dentaires avec leurs accessoires stériles et non stériles *Control modules (ultrasonic, motor) intended to be integrated in dental care electronic system with associated sterile and non-sterile accessories*			
SP NEWTRON	AM07	MD 1106	IIa
SP 4055 NEWTRON PMAX +	AM07-01	MD 1106	IIa
SP NEWTRON LED	AM08	MD 1106	IIa
XINETIC	PBAA	MD 1106	IIa

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

/vertimas iš anglų kalbos/

/logotipas: LNE – Le progrès, une passion à partager/

/logotipas: Certification Médical-Santé/

Notifikavimo įstaigos Nr. 0459

SERTIFIKATAS Nr. 21427, 7 peržiūra

Išduota 2017 m. liepos mėn. 10 d., Paryžiuje

CE SERTIFIKATAS

Pilnos Kokybės Užtikrinimo Sistemos aprobavimas
Pagal Direktyvos 93/42/EEB dėl medicinos prietaisų II PRIEDĄ, išskyrus 4 skyrių
III klasės prietaisams yra privalomas EC dizaino sertifikatas

Gamintojas

SATELEC
ACTEON GROUP įmonė
17 av. Gustave Eiffel
BP 30216
33708 MERIGNAC Cedex
PRANCŪZIJA

Prietaiso(-ų) kategorija

Medicininiai prietaisai ir elektromedicininiai prietaisai skirti odontologijai, elektrochirurginiai ir kaulų chirurgijos bei kaulų atstatymo prietaisai su susijusiais steriliais ir nesteriliais priedais

Papildoma informacija nurodyta priede

LNE/G-MED patvirtina, kad remiantis rezultatais, nurodytais byloje P159650-1, čia išvardintų medicininių prietaisų projektavimą, gamybą ir galutinę patikrą užtikrinanti Kokybės sistema atitinka Direktyvos 93/42/EEB II Priedo, išskyrus 4 skyrių, reikalavimus.

Sertifikato galiojimo laikas priklauso nuo periodinių ar netikėtų auditų rezultatų.

Įsigaliojimo data: 2017 m. liepos mėn. 28 d. (įskaitytinai)

Termino pasibaigimo data: 2020 m. liepos mėn. 27 d. (įskaitytinai)

/antspaudas:
LNE –
Laboratoire national
de métrologie et d'essais/

/parašas/

Pavaduojantis sertifikavimo direktorių
Cecile VAUGELADE
G-MED sertifikavimo skyriaus vadovas

LNE Nr. 21427, 7 peržiūra
Sertifikato Nr. 21427-6 pratęsimas

Prietaisų identifikacija

Prietaiso paskirtis / CE žymimi priedai	Komercinis prietaiso pavadinimas arba gaminio kodas	NBOG kodas	Medicinos prietaiso klasė
Valdymo konsolės (ultragarsinės, poliravimo oru ir/arba variklio) su susijusiais steriliais ir nesteriliais priedais, skirtais odontologijai (bendrąjai ir/arba intraoralinei chirurgijai)			
SUPRASSON P5 BOOSTER	AA10-05	MD 1106	IIa
P5 NEWTRON	AF48	MD 1106	IIa
P5 NEWTRON LED	AF015	MD 1106	IIa
P5 NEWTRON XS	AF52	MD 1106	IIa
P5 NEWTRON XS LED	AF016	MD 1106	IIa
NEWTRON BOOSTER	FBAB	MD 1106	IIa
NEWTRON P5 NEWTRON P5 B.LED	PBAC	MD 1106	IIa
NEWTRON P5 XS B.LED NEWTRON P5 XS B.LED BLUETOOTH	PBAD	MD 1106	IIa
VDW.ULTRA Standalone Ultrasonic	AF50-01	MD 1106	IIa
P5 PRO Ultra Piezo Ultrasonic	AF50-02	MD 1106	IIa
PROPHYMAX	AC21	MD 1106	IIa
AIR MAX	AC20	MD 1106	IIa
GENIUS	PO69	MD 1106	IIa
PIEZOTOME SOLO PIEZOTOME SOLO LED	PO23	MD 1106	IIa
PIEZOTOME 2	BE009	MD 1106	IIa
IMPLANT CENTER 2	PO24	MD 1106	IIa
PIEZOTOME CUBE	PO37	MD 1106	IIa
Valdymo moduliai (ultragarsiniai, variklio), skirti integruoti į dentalinės priežiūros elektronines sistemas su su susijusiais steriliais ir nesteriliais priedais			
SP NEWTRON	AM07-01	MD 1106	IIa
SP 4055 NEWTRON PMAX+	AM07-01	MD 1106	IIa
SP NEWTRON LED	AM08	MD 1106	IIa
XINETIC	PBAA	MD 1106	IIa

LNE/G-MED	0459

/antspaudas:
LNE –
Laboratoire national
de métrologie et d'essais/

/parašas/

Pavaduojantis sertifikavimo direktorių
Cecile VAUGELADE
G-MED sertifikavimo skyriaus vadovas

Laboratoire national de métrologie et d'essais · Pramoninė bei komercinė viešoji įstaiga LNE/G-MED · Notifikavimo įstaigos Nr. 0459
I, rue Gaston Boissier · 75274 Paris Cedex · Tel: 01 40 43 37 00 · Faks: 01 40 43 37 37 · www.lne.fr · www.gmed.fr