

Features

- 6.11.3.** 1 Three-way syringe (air/water/spray) with sterilisable tips
 - 6.11.3.** 3 instrument hoses
- Integrated spray water system for syringe and instruments (check valve prevents the back flow of water)
- 6.9.** 1 Spray water tank: 0.75 litres
 - 6.11.2.** Spray adjustment regulators for each instrument
 - 6.5., 6.11.3.** 1 High-performance suction hose 220 l/min. Continuously adjustable. Patent-pending BPR Swiss technology
- 6.6.** Adapter for saliva ejector tips and oral-dry-cup **6.7.**

- 6.4.,** 1 Suction fluid container: 1 litre (automatic overflow protection)

- 6.3.1.** Sturdy, air- and water-tight plastic construction, will not scratch, dent or corrode

Detachable front cover

- 6.10.** Disc type foot control

Integrated compressor: Capacity 75 l/min at 4 bar;
Sound pressure level: 48 dB; Compressed air tank: 4 litres

Technical Data

Air consumption instruments: 35–55 l/min

- 6.8.** Handpiece pressure: 2.5–3.5 bar

Each instrument is individually adjustable

Dimensions treatment position: 540mm × 530mm × 1070mm

Dimensions transport position: 540mm × 530mm × 760mm

Weight: 47 kg

- 6.2.** Case unit dimensions: 370mm × 190mm × 500mm

Case unit weight: 8 kg

Warranty: 2 years

Options: Light for instruments, electric scaler, curing light, electric micromotor, air motor, turbine, contra-angles, arm with tray, arm with lamp, DENTA-TROLLEY, DENTA-CASE etc.

6.

Combi-Port Premium

Mobile comfort

The COMBI-PORT PREMIUM offers you maximum performance and optimal comfort for treatments outside your dental clinic.

All optional instruments can be operated at full efficiency in continuous use, such as micromotors, turbines, scalers or even air polishers. The high-performance COMBI-PORT PREMIUM is rounded off by its highly efficient aspirator of 220 l/min (patent-pending BPR Swiss technology). The suction capacity is continuously adjustable. Compactly fitted into a trolley, after work the COMBI-PORT PREMIUM can easily be collapsed and wheeled to the next workplace like a suitcase. The high-performance COMBI-PORT PREMIUM compressor not only enables working throughout the day without interruption, but is also distinguished by its remarkably quiet operation (48 dB!).

Full performance of all handpieces

6.2. Self-contained high-performance suction 220 l/min



6.11.1.

Options Handpieces freely selectable 6.11.3.

6.3.2.

6.12. Silent oil-free high-performance compressor

- Continuous Operation
- Full Performance
- Plug-and-Play
- All-in-One
- Portable/Light

Combi-Port Premium



Rolling easy transport

6.3.3.

Option 30 freely selectable programs incl. 10 Endo

6.10.

Features

- » 1 Three-way syringe (air/water/spray) with sterilisable tips
- » Integrated spray water system for syringe and instruments (check valve prevents the back flow of water)
- » 3 instrument hoses
- » Spray adjustment regulators for each instrument
- » 1 Spray water tank: 1 litre
- » 1 High-performance suction hose with the patent-pending BPR Swiss technology (adapter for saliva ejector tips and oral-dry-cup)
- » 1 Suction fluid container: 1 litre (automatic overflow protection)
- » Pressure regulator-filter with hose (6 x 4 mm) to air source
- » Sturdy, air- and water-tight plastic construction, will not scratch, dent or corrode
- » Detachable front cover
- » Disc type foot control

6.12. » Integrated compressor Denta-Comp Premium – oil-free;

6.13. Capacity 75 l/min at 4 bar; Max. Pressure: 8 bar; Sound pressure level: 48 dB; Compressed air tank: 4 litres

6.14.

- » Integrated aspirator with the patent-pending BPR Swiss technology

Technical Data

- » Air consumption instruments: 35-55 l/min
- » Handpiece pressure: 2.5-3.5 bar
- » Each instrument is individually adjustable
- » Case unit weight: 8.0 kg
- » Case unit dimensions: 470 x 340 x 190 mm

6.12. » Stainless steel trolley with compressor weight: 34 kg

- » Stainless steel trolley with compressor dimensions: 520 x 520 x 750 mm

Warranty: 2 years

Options: Light for instruments, electric scaler, polymerisation lamp, electric micromotor, air motor, turbine, contra-angles, arm with tray, arm with lamp, etc.



8. Technical data

Voltage	220 V	6.1.
Weight	48.8 kg	
Dimensions Case-Unit	47 x 34 x 19 cm	
Dimensions stainless steel trolley with compressor	75 x 45 x 110 cm	6.17.
Instrument air consumption	35 – 55 l/min	
Instrument working pressure	2,5 – 3,5 bar	
Compressor pressure	5 bar	

9. Correcting malfunctions and servicing

9.1. Correcting malfunctions

Malfunction	Possible cause	Remedy
Device does not work	Plug is not plugged in	Plug in
Torque of the instrument is insufficient	Compression is too little	Regulate the compression
Suction does not work	Waste water bottle is full	Empty waste water bottle
Spray does not work	Spray water bottle is empty	Fill spray water bottle

9.2. Service

If problems occur with this product which cannot be resolved using the correction of malfunctions table or if a fault occurs, contact your service point or the manufacturer at following contact address:

Manufacturer service point:

BPR Swiss GmbH
Weststrasse 16
CH-3672 Oberdiessbach
0041 31 506 06 06
www.bpr-swiss.com
info@bpr-swiss.com

Synea Fusion:

Technical data



18.1.

Types:	TG-97 L / TG-97 L RM / TG-97 LM / TG-97 L N / TG-97	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 / -
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:	<ul style="list-style-type: none"> ① Roto Quick RM-connection ② Multiflex®** NSK Mach®** 	<ul style="list-style-type: none"> ① Roto Quick RM-connection ③ Multiflex®** NSK Mach®**
Head size:	Ø 10 mm	Ø 11.5 mm
Head height:	21.1 mm (with bur 19 mm)	21.4 mm (with bur 19 mm)
Power:	16 W	19 W
rpm (min ⁻¹):	390,000	360,000
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:	3 ± 0,3 bar	3 ± 0,3 bar
Multiflex® connection operating pressure:	2.5 to 4 bar	2.5 to 4 bar
Spray outlets:	4x	4x
Volume:	59 dB (A)	59 dB (A)

The power and rotary speeds of air drives depend greatly on the quality of the turbine hoses used and may therefore vary from the specified values.

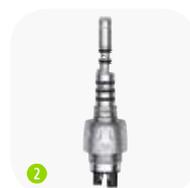
* Values apply for use of RM-34 LED with DC power supply

** Multiflex® and NSK Mach® are trademarks of third parties not affiliated with W&H Dentalwerk Bürmoos GmbH



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

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



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



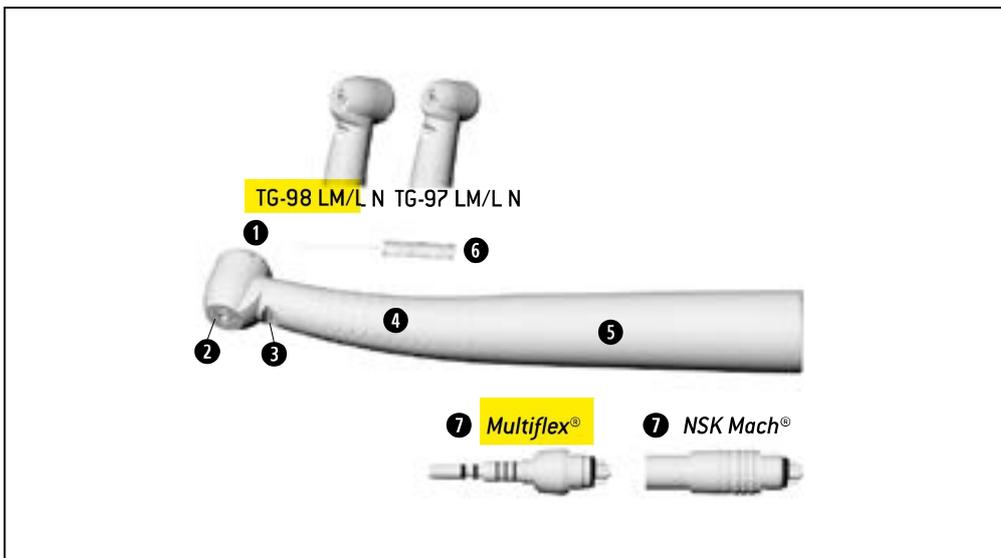
Instructions for use



syneq FUSION

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 Multiflex[®], NSK[®] connection



- 1 **Push-button** 18.1.
- 2 Spray nozzles
- 3 Compact glass rod
- 4 Grip profile
- 5 Sheath
- 6 Nozzle cleaner
- 7 **Connections**



Scan the QR code with your mobile phone for more information on Couplings

Diagrams, symbol photos, additional equipment and the content of illustrated accessories are not included in delivery.



Roto Quick couplings:	RQ-24	RQ-34	RQ-14	RQ-03	RQ-04
Light:	yes	yes	–	–	–
Spray control:	–	yes	yes	–	–
Connection:	6-hole	6-hole	Standard 4-hole	2 (3)-hole	Standard 4-hole

W&H Roto Quick couplings

Light, flexible and sterilizable: W&H Roto Quick couplings are versatile to use and are suitable both for instruments with LED+ and LED, as well as halogen light. 24 months of warranty.

18.1.

W&H coupling for

Multiflex®* connection: **RM-34 LED**

Light: **LED**

Spray control: yes

Connection: **6-hole**



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

Simple and uncompromising: The W&H coupling RM-34 LED is ready for immediate use. This means: The coupling with LED can be used alongside the conventional halogen couplings without requiring any changes at all in the dental unit. Long service life – 24 months of warranty.

* Multiflex® is a registered trademark of Kaltenbach & Voigt GmbH, Germany

W&H Dentalwerk Bürmoos GmbH
 Ignaz-Glaser-Straße 53, Postfach 1
 5111 Bürmoos, Austria
 t + 43 6274 6236-0
 f + 43 6274 6236-55
 office@wh.com
 wh.com

Intelligent oil + short maintenance intervals = longer lifespan

Diagrams, symbol photos, additional equipment and the content of illustrated accessories do not form part of the scope of supply.



Oil spray can

Type MD-400

Contents 400 ml

18.1.



Bottle for Assistina

Type MD-500

Contents 500 ml



Cartridge for Assistina 3x3 / 3x2

Type MD-200

Contents 200 ml

Order your Service Oil F1 through your dental supplier.
Suitable spray caps can be found on the Internet at wh.com

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, Postfach 1
5111 Bürmoos, Austria
t + 43 6274 6236-0
f + 43 6274 6236-55
office@wh.com
wh.com

TECHNICAL DATA

OPTIMA MX2^{INT} Sets

Main functions modifiable at all times

Selection of one of the 40 programmes, actual instrument speed, adjustable torque, handpiece ratio, with or without lighting, light intensity, selection of 5 languages

Optima MX2 ^{INT} set with DMX2 Pro Endo for 1 micromotor	Ref. 1700386-001
Optima MX2 ^{INT} set with DMX2 Pro Endo for 1 micromotor	Ref. 1700390-001 (with transformer)
Optima MX2 ^{INT} set with DMX2 Pro Endo for 1 micromotor	Ref. 1700391-001 (with converter)
Optima MX2 ^{INT} set with DMX2 Pro for 2 micromotors	Ref. 1700392-001 (with converter)
Optima MX2 ^{INT} set with DMX2 Plus for 1 micromotor	Ref. 1700393-001
Optima MX2 ^{INT} set with DMX2 Plus for 1 micromotor	Ref. 1700393-001 (with transformer)

DMX2 Sets

DMX2 Pro Endo set for 1 micromotor	Ref. 1700379-001
DMX2 Pro Endo set for 1 micromotor	Ref. 1700380-001 (with converter)
DMX2 Pro Endo set for 2 micromotors	Ref. 1700381-001 (with converter)
DMX2 Plus set for 1 micromotor	Ref. 1700376-001
DMX2 Plus set for 1 micromotor	Ref. 1700377-001 (with converter)
DMX2 Plus set for 2 micromotors	Ref. 1700378-001 (with converter)

10

18.2.

MX2 Micro-Series

Type	Brushless, with internal spray	18.2.
Max torque	3.5 Ncm	
Speed range	100-40,000 rpm	
Weight	94 gr	
Coupling	Compatible with Type E as per ISO 3964 and Micro-Series	
Light	LED with adjustable intensity	
Max noise level	53 dBA, compliant with ISO 11498	
Cleaning/Sterilisation	Sterilisable without protection	
Ref.	1600677-001	

MX2 hose

Type	A coupling rotating over 400°, in grey silicone
Diameter	10 mm
Standard length	1.7 m
Ref.	Ref. 1600700-001

Micromotor MX2



Instruction

REF 2100199-0004/2014.05/ENG

English

Medical devices entirely made in Switzerland by Bien-Air Dental SA.

Identification

Brushless electric micromotor. The most commonly used coupling in the world as per ISO Standard 3964 with internal spray and light with LED light.

Sterilisable motor

USA Caution: Federal law restricts this device to sale by or on the order of a dentist.

Intended use

Product intended for professional use only. Use in dentistry for prophylaxis, general dentistry and endodontics work and in the field of body care and health treatment. The device is not designed for use in an explosive atmosphere (anaesthetic gas). The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorised and may be dangerous. The medical device meets all the current legal requirements.

Technical data

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices. This medical device is in compliance with the legislation in force.

Electrical safety

According to IEC 60601-1 standard (General safety for Medical Electrical Equipment), the device shall be classified as a class II type B device.

Associated terminology is defined in sections 3.14 (3.13 if Class I) & 3.132 of the same standard. The following requirements as specified in IEC 60601-1 apply:

- Protection against electrical shock
- Ingress of liquids
- Protection against excessive temperatures and other safety hazards

Electromagnetic compatibility

Corresponds to the electromagnetic compatibility in accordance with IEC 60601-1-2. Declaration by the manufacturer regarding electromagnetic compatibility.

Hose Junction fig. 1

Hose with connector type MX2. Brushless type, 3-phase. Effective power according to the type of electronic power supply used. Synchronous motor with permanent magnets. Body of chromium and nickel-plated brass. Stainless steel nose.

Rphase

0.8 Ohm (included hose MX2 resistance).

Lphase

55 µH

Torque constant

6 mNm/ A rms

Back emf constant

6.5 mV/(rad/s).

Permanent 1.25 A rms

I max.5.0 A rms [10s]

Cooling

Through compressed air from the unit. Place the flowmeter on the connector and set 10 to normliter/ min. fig. 2.

Air consumption output

10 NI/min (+/-10%).

Dimensions

Ø 21.2 x 73.5 mm (0.83 x 2.90 inches) including the nose attachment.

Coupling

Nose in accordance with ISO 3964, with internal spray and light.

Weight

94 g (3.18 oz) without the cable.

Operating times

According to the type of electronics used.

Noise level

In accordance with ISO 11498, less than 53 dBA at 45 cm (17.72 in).

Recommended rotation speed

Max. 40.000 rpm.

Direction of rotation

Clockwise and anticlockwise.

Torque

Depending on the type of electronic controller used.

Light

LED, variable from 10 klux to 38 klux.

Assembly

Important

Never connect an instrument on a running micromotor.

Changing the seals, fig. 3

Disposal

This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

Maintenance

Important

- The instrument is delivered "non sterile".
- Before using for the first time and within a maximum of 30 minutes after each treatment, clean, disinfect the attachment, then sterilise. Observing this procedure eliminates any blood, saliva or saline solution residues.
- Do not immerse in an ultrasonic bath.
- **Do not clean in a washer-disinfectant unit fig. 8.**
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

In the event of prolonged disuse, the instrument must be stored in a dry environment. Clean and sterilise the instrument before reuse.

Precautions of use

6 dalis

The standard precautions in particular wearing individual protection equipment (gloves, glasses...), must be complied with by healthcare personnel working with contaminated or potentially contaminated medical instruments. Pointed and sharp instruments should be handled with great caution.

Check that the steriliser and the water that is used are clean. After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion.

We recommend that the motor is cleaned and sterilised as described below before the initial first use and subsequently after each treatment.

1 Cleaning

The external surface of the motor must be cleaned to remove impurities as follows fig. 4.

- Hold the motor by the nose under running water (< 25°C) as shown in the diagram below
- With the aid of a soft bristled brush, clean the external surface of the motor.
- Avoid allowing water to enter internally into the motor either by the the nose or hose connector.

2 Disinfection

Carefully rub the external surfaces of the motor, for approximately one minute, with a soft bristle brush impregnated with a detergent or disinfectant solution fig. 5.

The motor must be rinsed as follows fig. 4

- Hold the motor by the nose under running water (< 25°C) as shown in the diagram below
- Avoid allowing water to enter internally into the motor either by the the nose or hose connector.

Suitable detergents

- Detergent or detergent-disinfectant (pH 6- 9.5) recommended for cleaning-disinfection of dental or surgical instruments.
- Quaternary ammonium- and/or enzyme-based surfactants.
- Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- Do not soak in physiological liquid (NaCl).

3 Sterilisation

Do not use a sterilisation procedure other than the one described below.

Procedure: Fractionated pre-vacuum steam sterilisation, Class B cycle acc. to EN13060. The procedure has been validated according to ISO 17664. All Bien-Air Dental straight handpieces are sterilisable in an autoclave up to 135°C (273.2°F). Duration: 3 or 18 min., depending to the national requirements in force. **18.2.**

Important

The quality of the sterilisation depends very much on the cleanliness of the device. Only perfectly clean devices may be sterilised fig. 6.

The instrument will function in excess of 500 sterilisations.

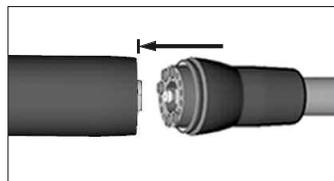


fig. 1a

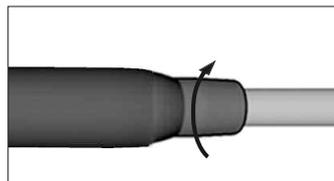


fig. 1b



fig. 2

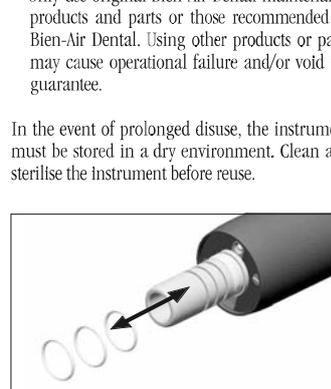


fig. 3



fig. 7

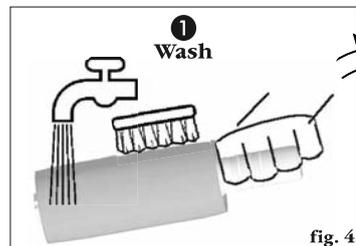


fig. 4

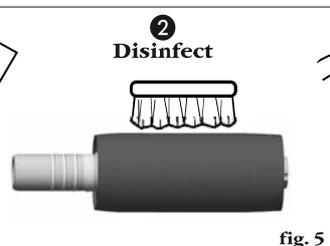


fig. 5



fig. 6

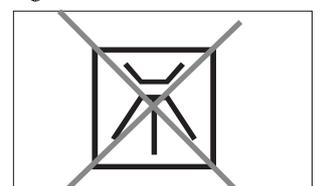
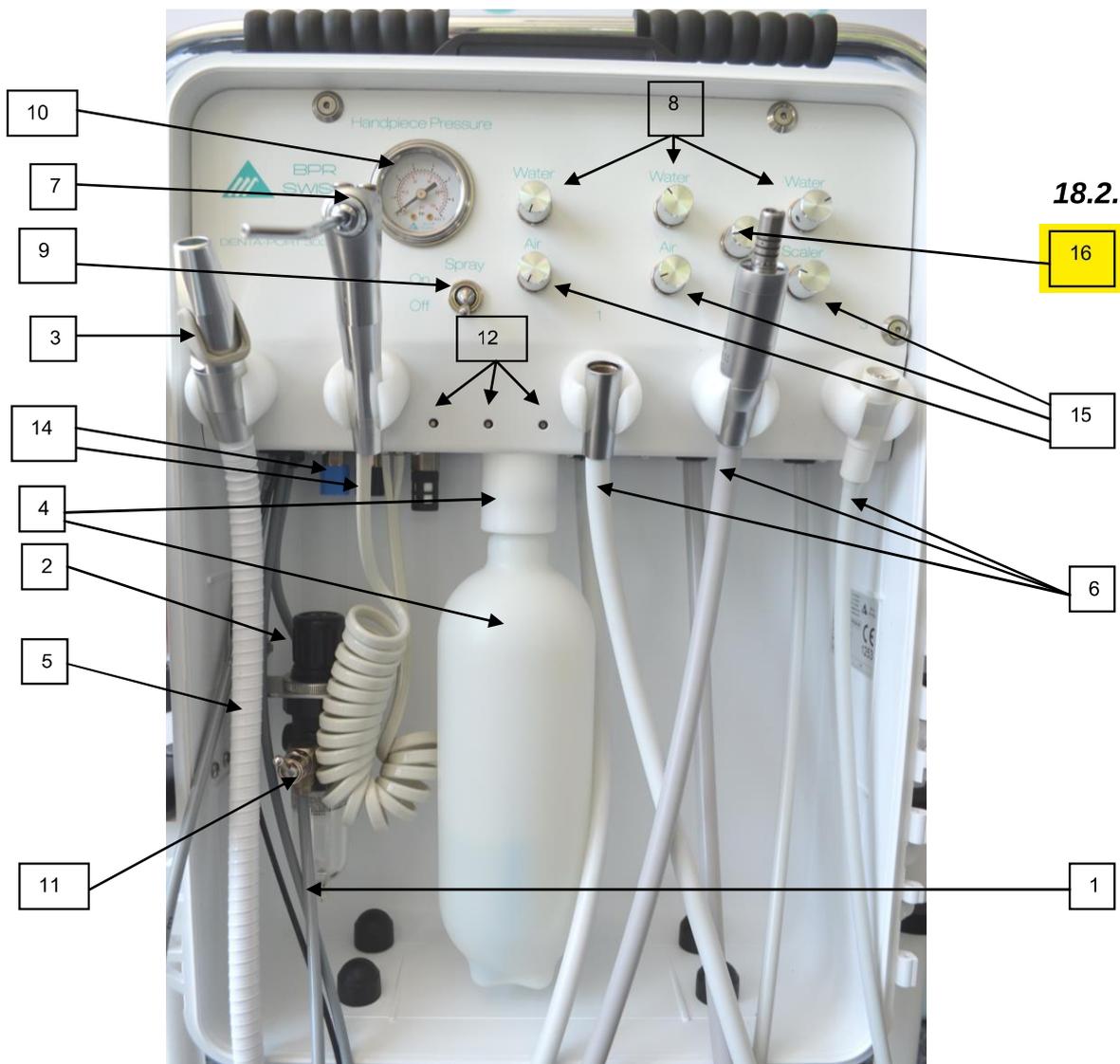


fig. 8

4.3. Version with electric motor



4.5. Caption

- 1** Connection to air source
- 2** Master pressure adjustment with filter and moisture drain hose
- 3** Adjustment lever for saliva suction
- 4** Spray water container / spray water container mounting
- 5** Saliva ejector hose
- 6** Instrument hoses
- 7** 3 way syringe
- 8** Spray-water adjustment knobs
- 9** Spray water ON/OFF
- 10** Pressure indicator for instruments
- 11** Master ON/OFF
- 12** Pressure adjustment for instruments
- 13** Pressure adjustment for instrument and scaler
- 14** Connection foot pedal
- 15** Spray-air adjustment knobs
- 16** Speed regulator for electric motor **18.2.**
- 17** Spray water adjustment for scaler
- 18** Fine adjustment intensity scaler

Synea Fusion:

Technical data



	18.4. WG-99 LT	WG-66 LT	18.3. WG-56 LT	HG-43 A	WG-67 LT	WG-69 LT
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	–	–	–
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	1:1	2:1	2:1
Spray:	4x (> 50 ml/min)	1x (> 50 ml/min)	1x (> 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	–	25,000 lux	25,000 lux
Indications:	<ul style="list-style-type: none"> > Crown and cavity preparations > Trephining > Resections > Finishing > Removing fillings and metal 	<ul style="list-style-type: none"> > Excavating > Preparations close to the pulp > Finishing 	<ul style="list-style-type: none"> > Crown and cavity preparations > Trephining > Resections > Separating > Finishing of cavity margins and fillings 	<ul style="list-style-type: none"> > Preparing > Separating > Trephining > Resections in anterior area > Minor technical procedures 	<ul style="list-style-type: none"> > Removal of excess materials > Prepolishing > Fine polishing > Buffing in the interdental and subgingival areas > Max. rotational speed 20,000 rpm 	<ul style="list-style-type: none"> > Finishing of interproximal and subgingival areas and cavity margins > Chamfering of the preparation edges and of cavities > Removal of subgingival plaque > Stripping in orthodontics > Max. rotational speed 40,000 rpm

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	compact electric high-speed	1:4.5	180,000	Push-button 1.6mm friction grip burs		5	9.1	13.2	21.2	66	87	
	standard electric high-speed											
	compact electric low-speed	1:1	40,000	Push-button 2.35mm latch burs	yes	1	9.5	12.5	20.0	66	87	
	standard electric low-speed											
	standard electric straight											
standard electric high-speed	1:5	200,000	Push-button 1.6mm friction grip burs		4	9.5	14.5	21.7	74			
standard electric low-speed												
standard electric low-speed												
standard electric low-speed	1:1	40,000	Push-button 1.6mm friction grip burs	yes	1	9.9	15.5	22.2	70	96		
standard electric low-speed												
standard electric low-speed												
standard electric low-speed	2:1	20,000	Push-button 2.35mm latch burs			9.5	13.5	21.5	68			
standard electric low-speed												
standard electric straight	1:1	40,000	Twist-tension 2.35 mm lab burs	No	1	n/a	n/a	n/a	n/a	77		
Synea 400 Series	A-dec W&H air low-speed	1:1	20,000	Push-button 2.35mm latch burs					20.7			
	A-dec W&H air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs			10.1	13.01	22.4	42	87.9	
	A-dec W&H air low-speed	4:1	5,000	Push-button 2.35mm latch burs					20.7			
	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	
	Midwest compatible air low-speed	1:1	20,000	Push-button 2.35mm latch burs	No	No	10.1	13.01	20.7		87.9	
	Midwest compatible air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs					22.4			
	Midwest compatible air straight	1:1	20,000	Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	41	78.2	
	StarDental compatible air low-speed	1:1	20,000	Push-button 2.35mm latch burs					20.7			79.7
	StarDental compatible air low-speed	1:1	20,000	Push-button 1.6mm friction grip burs			10.1	13.01	22.4			
	StarDental compatible air straight	1:1	20,000	Twist-tension 2.35 mm lab burs			n/a	n/a	n/a	39	66.9	
	Algebra 300 Series											

18.4.

18.3.

ULTRASONIC



ULTRASONIC

NEWTRON LED



18.5.

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

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

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

Power supply	24VAC ±10% 35VA / 35VDC ±10%
Frequency	28 to 36 KHz
Perio	8 to 30 mA
Endo	32 to 54 mA
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](#)

Features

The smart system of DENTA-CHAIR 303 allows setting up or stow away the chair within 30 seconds

Moving like a trolley: After folding, the chair can be easily pulled with the telescopic handle

Comfortable upholstery with premium covering

Upholstery available in many different colours

The smooth backrest adjustment is stepless and synchronous with the automatic legrest adjustment

Double articulated headrest adjustment

Technical Data

Weight: 18 kg

Dimensions: 580mm × 380mm × 650mm

Warranty: 2 years

Options: SUN-LED (LED mobile dental operatory light), Arm with tray, Armrests etc.

19.

Denta-Chair 303

The most comfortable mobile treatment chair in the world

DENTA-CHAIR 303 fulfils perfectly all of the requirements for a mobile treatment chair.

Its intelligent design and high-quality finish come together to make a robustly constructed, yet comfortable and impressively light treatment chair that is easy to transport and quick to assemble and disassemble.

19.

Comfortable lying surface

Variable headrest

18 kg

Very robust construction



Built-in roll function



Options: Treatment light, Tray



Set up / disassembly in 30 seconds



Stepless adjustment position

Continuous Operation

Plug-and-Play

Mobile/Rollable

20.

The **DENTA-DOCTOR STOOL 303** from BPR.
Sit comfortably. Disassemble. Transport.



DENTA-DOCTOR STOOL 303

Features

» The Denta-Doctor Stool 303 is set up or stowed away in less than 30 seconds

» To comfortably transport, it can be stowed away in a convenient carrying bag

» Height adjustment by means of a gas spring

» Comfortable upholstery with premium covering. Available in a lot of different colours

Technical data

» Weight: 5.65 kg

» Diameter Seat: 340 mm

» Height adjustable: 500 x 630 mm

Options: Arm / Back rest

Warranty: 2 years

EYEZOOM™ ADJUSTABLE MAGNIFICATION LOUPE

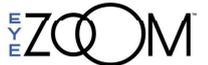
FIRST & ONLY LOUPE TO OFFER MULTIPLE MAGNIFICATION POWERS



SPECIFICATIONS **21.**

Series	Power	Field Width	Field Depth	Working Distance	Weight*
EyeZoom	3x	4.0" (10.16 cm)	4.0" (10.16 cm)	Customized to each user	3.4 oz (97.5 g)
	4x	3.25" (8.26 cm)	3.25" (8.26 cm)		
	5x	2.5" (6.35 cm)	2.5" (6.35 cm)		

Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.
*Measured on Orasoptic Legend frame.



21.

The EyeZoom™ loupe offers adjustable magnification levels ranging from 3x-5x power. Developed to assist healthcare professionals view an operating site from multiple perspectives, the loupe conforms to fit each user's individual preference.

MOUNTING OPTIONS
Through-the-Lens

FRAME OPTIONS
Legend™ • Rave™ • Rydon™ • Victory™ • XV1™



ADJUSTABLE MAGNIFICATION
3-step variable magnification technology between 3x, 4x and 5x power



QUALITY ENGINEERING
Optics co-engineered by Orasoptic™ and Konica Minolta®



UNPRECEDENTED OPTICAL DESIGN
Enhanced visual acuity and high-definition resolution



No Magnification 3x 4x 5x



No Magnification 3x 4x 5x

Patent Pending. Konica Minolta® is a registered trademark of Konica Minolta, Inc. Used with permission.

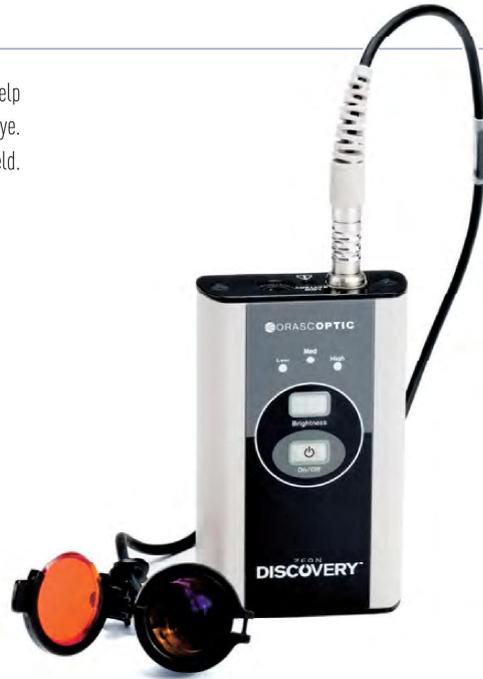


DISCOVERY™ HEADLIGHT

The Discovery is our brightest portable headlight system; providing a precise focused light to help you navigate your work area and illuminate critical details that can be missed by the naked eye. When coaxially mounted to your loupes, the system eliminates shadows from the operating field.

FEATURES

- Constant current technology
- Push button controls
- Sleek battery pack design
- 3 intensity levels up to 7,000 foot candles



SPECIFICATIONS 22.

Series	Light Intensity	Intensity Control	Headlight Weight	Battery Type	Battery Weight	Battery Life	Charging Time
Discovery	3000/5000/7000 ft cd	3 intensity levels	0.6 oz (18.1 g)	Lithium Ion	9.6 oz (273.3 g)	Up to 17 hours	Up to 3 hours



HEADBAND | FRAMES

RIGID HEADBAND 22.



This durable and lightweight headband offers tension control for the top and circumference of the head.

- MOUNTING OPTIONS**
 Flip-up • Headlight
- SIZE**
 One Size
- LOUPE OPTIONS**
 HDL™ 2.5, 3.0 • HiRes™ 2
 HiRes Plus™

CLOTH HEADBAND



This simple elastic fabric headband offers a sliding mount that can support telescopes or a headlight

- MOUNTING OPTIONS**
 Flip-up • Headlight
- SIZE**
 One Size
- LOUPE OPTIONS**
 HDL 2.5, 3.0 • HiRes 2



OPERATING INSTRUCTIONS

Discovery™ Portable LED Light System

9. Install the curing filter (if needed).
- Slide the filter's frame over the outer rib of the headlight so that the hinged frame can flip down in front of the headlight as shown in the figure to the right.
 - Slide the filter into the groove provided in the hinged frame.
 - The filter can now be flipped down in a position in front of the headlight.



5. Technical Data

Weight of the reflector lamp	Approximately 0.7 ounces (20 grams)
Weight of control unit	Approximately 8.5 ounces (240 grams)
Diameter of the reflector lamp	Approximately 1.0 inch (26 mm)
Dimensions of control unit	Height approximately 3.8 inches (97 mm) Width approximately 2.5 inches (64 mm) Depth approximately 1.0 inch (26 mm)
Equipment class	II 
Ingress of water	(ordinary equipment) IXPØ
Battery type	Li-Ion battery, 7.4 V/ 2,400 mAh
Battery charge time	3 hours
Battery life	Low – approximately 17 hours Medium – approximately 10 hours High – approximately 7 hours
Light intensity	Measured at a distance of 12 inches: Low – 3,000 foot candles Medium – 5,000 foot candles High – 7,000 foot candles
Operation mode	Continuous
EMC	IEC60601-1-2, Class B, EN55011
Safety	IEC 60601-1
Protection from shock	Type BF  Internally powered
Temperature for operation and storage	32° to 95° F (0° to 35° C)

22.



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 audit documented in the report dated October 19, 2016.

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.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: December 20, 2016

This SQS Certificate is valid up to and including February 28, 2019
Registration number 43311
Approved Medical Responsible:
December 15, 2016


R. Gläuser, CEO SQS


K. Schulze, Medical Responsible



Trusted Cert



Notified Body 1250



Swiss Made



**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
0297

Identification no. / Kennnummer / Identificación N°:

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/Ciente del proyecto

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

EC DECLARATION OF CONFORMITY

Medical Device Family: **Electric Micromotors**

The manufacturer,

Bien-Air Dental SA

Länggasse 60
CH-2504 Bienne
Switzerland,

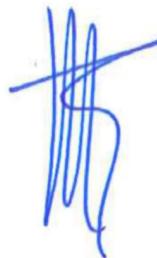
declares under its sole responsibility that the medical devices listed below meet the provisions of the European Medical Device Directive 93/42/EEC which apply to them and that Annex II (excl. section 4) of the aforementioned directive has been followed for their conformity assessment.

Notified Body

SGS United Kingdom Ltd
202B Worle Parkway,
Weston-super-Mare
BS22 6WA, UK

CE Marking

CE 0120



Mrs Helena LACALLE
Regulatory Affairs Manager

Reference #	Device Designation	Class*	Rule*
1600458-001	HOSE B-4VR 400 1.7M	IIa	9
1600605-001	MOT MX LED	IIa	9
1600606-001	CABLE MX LED	IIa	9
1600633-001	MOT MC2 40 GT IR	IIa	9
1600677-001	MOT MX2	IIa	9
1600678-001	HOSE MX2 GREY	IIa	9
1600680-001	MOT MC3 (LED)	IIa	9
1600681-001	MOT ISOLITE (LED)	IIa	9
1600695-001	HOSE 4VX SURF6 ADEC	IIa	9
1600700-001	HOSE MX2 400 GREY	IIa	9
1600751-001	MOT MCX LED	IIa	9
1600752-001	MOT MX CHIROPRO	IIa	9
1600753-001	COUPLING SOCKET B-MX2	IIa	9
1600754-001	HOSE B-MX2 GREY	IIa	9
1600755-001	MOT MX-i LED	IIa	9
1600756-001	HOSE MCX GREY	IIa	9
1600762-001	HOSE B-MX2 GREY	IIa	9
1600780-001	MOT MCX	IIa	9
1600820-001	HOSE MCX GREY ADEC	IIa	9
1600824-001	HOSE B-MCX GREY	IIa	9
1600825-001	MOT MX-i	IIa	9
1600875-001	MOT MX-i LED	IIa	9
1600881-001	CABLE MX LED 3M	IIa	9
1700043-001	SET B-4VR400 GREY+SOCKET B	IIa	9
1700046-001	MC3 LK + 4VR400	IIa	9
1700074-001	SET MOT BASCH+CABLE	IIa	9
1700336-001	MC3 LK + 4VLM	IIa	9
1700337-001	SET MC3 IR + 4VLM-11 GREY	IIa	9
1700445-001	SET MC3 LED + 4VR400 GREY	IIa	9

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-ángulo
(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
0297

Identification no. / Kennnummer / Identificación N°:

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/Ciente del proyecto

Description / Bezeichnung / Descripción	Type/Tipo	REF	SN <i>(from/ab/desde)</i>
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

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 certificat 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 above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification 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)



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

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

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

Identification des dispositifs / Identification of devices

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

LNE/G-MED 0459



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

ADD

720 DM 0701-31 rev 5 du 28/07/2015

BPR Swiss GmbH Telephone: +41 31 506 06 06
Dental Mobility Telefax: +41 31 506 06 00
Weststrasse 16 Service Center: +41 31 506 06 01
CH-3672 Oberdiessbach E-mail: info@bpr-swiss.com
Switzerland Internet: www.bpr-swiss.com



EG-Konformitätserklärung / EC-Declaration of Conformity

Name und Adresse der Firma BPR SWISS GMBH
Name and address of the firm Weststrasse 16
CH-3672 Oberdiessbach
Switzerland

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

die Medizinprodukte DENTA-CHAIR 303, DENTA-DOCTOR STOOL 303
the medical devices

Portable und mobile Dentalbehandlungsgeräte
Portable and mobile dental operatory units

Bezeichnung, Typ oder Modell, Chargen- oder
Seriennummer, ev. Herkunft u. Stückzahl
Name, type or model, batch or serial number,
possibly sources and number of items

der Klasse I
of class

aufgrund deren Konzipierung und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den grundlegenden Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entsprechen.

by reason of its constructions meets all the provisions of the directive 93/42/EEC which apply to it.

Konformitätsbewertungsverfahren Anhang VII MDD, 1,7
Conformity assessment procedure Appendix VII MDD, 1,7

Konformitätsbewertungsstelle Schweizerische Vereinigung
(falls beigezogen) für Qualitäts- und Management-Systeme (SQS)
Notified body (if consulted) CE 1250
Bernstrasse 103
CH-3052 Zollikofen

A handwritten signature in blue ink, appearing to read 'M. Maurer', is placed above the printed name and title.

Marcel Maurer
Geschäftsführer & CTO
Managing Director & CTO
Name und Funktion

Oberdiessbach, 20.12.2017
Ort, Datum / Place, date

Gültig bis / valid until: 28.02.2019

Diese Konformitätserklärung gilt in Verbindung mit dem mitgelieferten Produkt und der zugehörigen Seriennummer.

This declaration of conformity is valid in connection with the supplied product and the corresponding serial number.