



EC DECLARATION OF CONFORMITY

DEC-960920-revC

This declaration of conformity is issued under the sole responsibility of the manufacturer

• Manufacturer's Name:	Metrex Research, LLC dba Orasoptic
• Manufacturer's Address:	3225 Deming Way, Suite 190 Middleton, WI 53562 USA
• Authorized Representative within the Community:	Kerr Italia, Srl Via Passanti, 332 I-84018 Scafati (SA), Italy
• Device Classification:	Class I
• Model:	Orasoptic Loupes
• Product Number(s):	Defined by Oracle Configurator, see CE technical file for details.
• Device Identification:	000000-999999
• Application of Council Directive(s):	93/42/EEC as amended by 2007/47/EC 2011/65/EU
• Standard(s) to which Conformity is Declared:	EN 50581:2012 EN 62321:2009 ISO 13485 ISO 14971
The object of the declaration described above is in conformity with Directive 93/42/EEC concerning medical devices as amended by 2007/47/EC, and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.	
Date of Issue:	February 28, 2014
Place of Issue:	Metrex Research, LLC dba Orasoptic, Middleton, WI USA
 James Onderak, Director of I2E	 James Chenard, Director of Quality



Product Catalog

SURGEONS DENTISTS HYGIENISTS

orascopic.com



OUR VISION

See results from recent
LAB TESTS!
See page 22

AT ORASCOPTIC, WE ENVISION every healthcare procedure in the world being performed with superior visualization under the best ergonomic conditions for the clinician to drive the best patient outcomes.

Recognized as a pioneer in medical vision for over 35 years, Orasoptic continues to offer healthcare professionals superior products that focus on magnification and illumination.

- Our legacy of advanced performance and clinician-first features sets the bar for craftsmanship, innovation and durability.
- Each Orasoptic loupe is custom-crafted with meticulous precision in Madison, Wisconsin and personalized to the individual’s facial geometry, ensuring optimal resolution across the widest and deepest field of view.
- Engineered with performance and comfort in mind, our loupes employ rich details such as adjustable nose pads, flexible temple hinges, anti-reflective lens coatings and working distances refined in half-inch increments. Additionally, steep declination angles allow for improved posture and help reduce strain.

Discover how Orasoptic continually shatters the status quo with award-winning optical innovations such as the EyeZoom™ loupe with three adjustable magnification levels and the XV1™ loupe, the first and only all-in-one wireless loupe & headlight.

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LOUPES

HDL™ 2.5 MICRO

Pushing the boundaries of a typical micro optic, the loupe provides a generous field of view with edge-to-edge clarity. The exceptionally small profile also allows for additional viewing space above the telescope.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

ErgoEdge™ · Flak 2.0® · Rydon™ · Tempo™
Victory™ · XVI™



HDL™ 2.5 MACRO

Delivering an equivalent image quality to the HDL 2.5 Micro, the HDL 2.5 Macro distinguishes itself with sizeable field width that allows instruments to be transitioned into the field of view with ease.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

ErgoEdge™ · Flak 2.0® · Rydon™ · Tempo™
Victory™ · XVI™



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
HDL Micro	2.5x	Customized to each user	3.4" (8.75 cm)	7.0" (17.80 cm)	TTL 1.36 oz (38.60 g)
HDL Macro	2.5x	Customized to each user	4.0" (10.40 cm)	5.0" (12.70 cm)	TTL 1.80 oz (50.70 g)

* measured on Orascope Victory Frame, see pg 13



HDL™ 3.0

Comparable to its predecessor — the HDL™ 2.5 — this custom-crafted loupe boasts edge-to-edge clarity and a generous field of view. Compact and lightweight, this loupe is designed to deliver a comfort rarely associated with Galilean optics of equivalent magnification power.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

ErgoEdge™ · Flak 2.0® · Rydon™ · Tempo™
Victory™ · XVI™



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
HDL	3.0x	Customized to each user	3.1" (7.90 cm)	7.5" (19.0 cm)	TTL 1.70 oz (48.70 g)

** measured on Orasoptic Victory Frame, see pg 13*



LOUPES

HDL™ PRISMS

Prismatic Expanded Field Loupes — Ranging from 3.5x to 5.5x, these loupes are designed for healthcare professionals who perform exacting procedures. The HDL prisms enable precise interactions, enhanced visibility and provide a customizable declination angle that accommodates various surgical procedures. The compact design and brushed metallic finish of the telescope offers an aesthetically pleasing element to this medical device.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

ErgoEdge™ · Rydon™ · Tempo™ · Victory™ · XVI™



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
HDL	3.5x	Customized to each user	3.5" (8.90 cm)	3.6" (9.10 cm)	TTL 2.4 oz (67.5 g)
	4.5x	Customized to each user	2.95" (7.50 cm)	2.64" (6.70 cm)	TTL 2.5 oz (71.5 g)
	5.5x	Customized to each user	2.51" (6.40 cm)	2.32" (5.90 cm)	TTL 2.6 oz (74.4 g)

* measured on Orascope Victory Frame, see pg 13



LOUPES INTERCHANGEABLE MAGNIFICATION



OMNIOPTIC™

Discover the first and only interchangeable magnification loupe that allows clinicians to select the optimal magnification power for each procedure. Accommodating four magnification powers ranging from 2.5x – 5.5x, the OmniOptic is an ideal system for users looking to increase their magnification power over the course of their career.



MOUNTING OPTIONS

Through-the-Lens

LOUPE OPTIONS

HDL™ 2.5 Macro • HDL 3.5 • HDL 4.5 • HDL 5.5

FRAME OPTIONS

ErgoEdge™ • Rydon™ • Tempo™
Victory™ • XVI™

SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Weight*
OmniOptic	2.5x	Customized to each user	2.02 oz (57.3 g)
	3.5x	Customized to each user	2.66 oz (75.3 g)
	4.5x	Customized to each user	2.79 oz (79.1 g)
	5.5x	Customized to each user	2.90 oz (82.1 g)

* measured on Orasoptic Victory Frame, see pg 13



OPTICS ADJUSTABLE MAGNIFICATION

EYEZOOM™ & EYEZOOM™ MINI

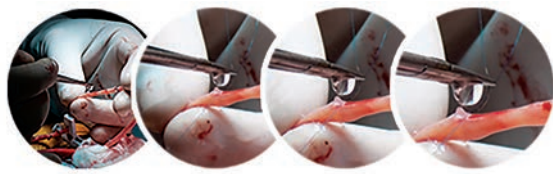
Offering two adjustable magnification solutions, EyeZoom™ features three magnification levels ranging from 3x-5x, while EyeZoom Mini™ features two magnification levels allowing the user to switch between 2.5x and 3.5x. Orascope's EyeZoom and EyeZoom Mini offer clinicians the ability to switch between multiple magnification powers to

accommodate a variety of procedures that require varying degrees of detail. Use lower magnification for routine dental examinations and preparation for crown and bridge procedures. Increase magnification for more complex and exacting procedures.



EYEZOOM ADJUSTABLE MAGNIFICATION

EyeZoom employs 3-step variable magnification



No
magnification

3x

4x

5x



EYEZOOM MINI ADJUSTABLE MAGNIFICATION

EyeZoom Mini employs 2-step variable magnification



No
magnification

2.5x

3.5x

QUALITY ENGINEERING

Optics co-engineered by
Orascope™ & Konica Minolta™





The first ever 3-in-1 and 2-in-1 adjustable magnification loupes, EyeZoom and EyeZoom Mini were developed to assist healthcare professionals view an operating site from multiple perspectives, conforming to fit each user’s individual preference.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

ErgoEdge™ · Rydon™ · Tempo™ · Victory™ · XV1™



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
EyeZoom	3.0x	Customized to each user	4.0" (10.20 cm)	4.0" (10.20 cm)	TTL 3.4 oz (97.6 g)
	4.0x	Customized to each user	3.25" (8.30 cm)	3.25" (8.30 cm)	
	5.0x	Customized to each user	2.50" (6.35 cm)	2.50" (6.35 cm)	
EyeZoom Mini	2.5x	Customized to each user	3.97" (10.10 cm)	4.76" (12.10 cm)	TTL 2.6 oz (73.7 g)
	3.5x	Customized to each user	3.19" (8.10 cm)	3.78" (9.60 cm)	

** EyeZoom measured on Orascopic Legend Frame; EyeZoom Mini measured on Orascopic Victory Frame, see pg 13*



HYGIENE LOUPES

RDH ELITE™

Orasoptic's first loupe with a singular focus on the dental hygiene industry. Designed by a team of both practicing hygienists and industry-recognized experts in ergonomics and infection control, the RDH Elite is centered on improving ergonomics and productivity.

MOUNTING OPTIONS

Through-the-Lens

FRAME OPTIONS

Iconic · Sport



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
RDH Elite	2.5x	Customized to each user	4.0" (10.20 cm)	6.0" (15.20 cm)	TTL 1.9 oz (58.4 g)

** measured on Orasoptic RDH Iconic Frame, see pg 13*



RDH ELITE EDGE™

Ergonomic focus — Accommodates steep telescope declination for proper posture.

Optimal Field of View — Encompasses a field width and depth recommended for dental hygiene professionals.

Infection Protection — Deep carrier lens and custom-designed side shields provide additional protection from debris and backsplash.

Fashionable — Iconic frame styles feature interchangeable temple tips and color emblems allowing you to add your own personal style.



RDH EliteEdge frame



RDH EliteEdge frame

SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
RDH EliteEdge	2.5x	Customized to each user	4.0" (10.20 cm)	6.0" (15.20 cm)	TTL 1.5 oz (43.3 g)

** measured on Orasoptic RDH Elite Edge Frame, see pg 13*



FLIP-UP LOUPES

UNIVERSAL FLIP-UP™

Flip-ups generally afford steep declination angles up to 55 degrees. Our design features a vertical slide that allows advanced flexibility to position the telescopes in front of the pupils. They are assembled to the customer's PD at factory, but the horizontal PD bar allows the user to fine-tune

convergence. The “universal flip” feature allows the customer to transfer the telescopes to a variety of different eyewear. If worn on ophthalmic eyewear, the customer's prescription is updated every time they purchase a new pair of glasses.

MOUNTING OPTIONS

Flip-up

LOUPE OPTIONS

HDL™ 2.5 Macro

FRAME OPTIONS

Titan

COMPATIBLE WITH ...

Safety Glasses · Leaded Glasses (North America only)
Ophthalmic Glasses (your *own* eyewear!)

SPECIFICATIONS

Field Weight	Field Depth	Weight
4.0" (10.40 cm)	5.0" (12.70 cm)	2.5 oz (70.9 g)



FRAMES

ICONIC

TEMPO™



MATERIAL Stainless Steel · Aluminum

MOUNTING OPTIONS Through-the-Lens

SIZES Small · Medium · Large



Black



Blue



Merlot



Slate



Twist

Unlimited prescriptions

VICTORY™



MATERIAL Titanium

MOUNTING OPTIONS Through-the-Lens

SIZES Small · Medium · Large



Black



Blue



Merlot



Slate

Unlimited prescriptions



FRAMES SPORT

ERGOEDGE™



MATERIAL Nylon-blend branded Grilamid

MOUNTING OPTIONS Through-the-Lens

SIZES Small • Medium



Black

Blue

Carbon



Merlot

Purple

Tortoise

Wide range of prescriptions, including bifocals

RYDON™



MATERIAL Advance Carbon, Magnesium, Silicium, Grilamid, and Titanium

MOUNTING OPTIONS Through-the-Lens

SIZES One Size



Black

Blue

Carbon



Merlot

Platinum

Tortoise

Wide range of prescriptions, including bifocals

FLAK 2.0®



MATERIAL Oakley® O-Matter

MOUNTING OPTIONS Through-the-Lens

SIZES One Size



Black

Wide range of prescriptions, including bifocals

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HEADLIGHTS

Orasoptic was granted a U.S. patent for the optical design used in each of its headlamps. This means we offer our customers a highly uniform spot with the least amount of weight in comparison to other

solutions on the market (see below). With Orasoptic-exclusive technology, clinicians can flood oral and surgical sites with a more uniform distribution of light, using an optical design that is lighter weight than before — that’s a win-win!



ORASOPTIC

Each Orasoptic headlight model is tested to ensure compliance with blue light testing standards set by the International Electrotechnical Commission. To learn more, visit orasoptic.com/products/headlights.



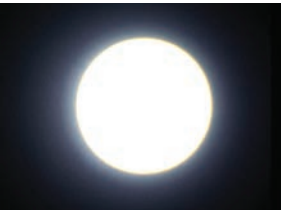
Manufacturer A



Manufacturer B



Manufacturer C



Manufacturer D

Based on results of independent third-party testing.



HEADLIGHTS

LOUPE & LIGHT

XV1™

Designed with a perfect synergy between magnification and illumination, the XV1 is the **first and only** wireless loupe and headlight in one. Employing our lightest weight headlight, this frame has no exterior cabling and draws its power from battery packs in the temple tips. The counterbalanced design enhances overall comfort.



Black



Blue



Merlot



Steel



White



SPECIFICATIONS Each XV1 includes power supply, charger, 4 rechargeable batteries, carrying case, 2 optical screwdrivers, cleaning cloth, curing filter.

Series	Weight	Light Intensity	Battery Life (4)	Charging Time
XV1	5.7 oz (161.7 g)	Low: 42 Lumens High: 68 Lumens	10 hrs on low 6 hrs on high	Less than 2 hours

All Orasoptic telescope models can be mounted on the XV1 frame.



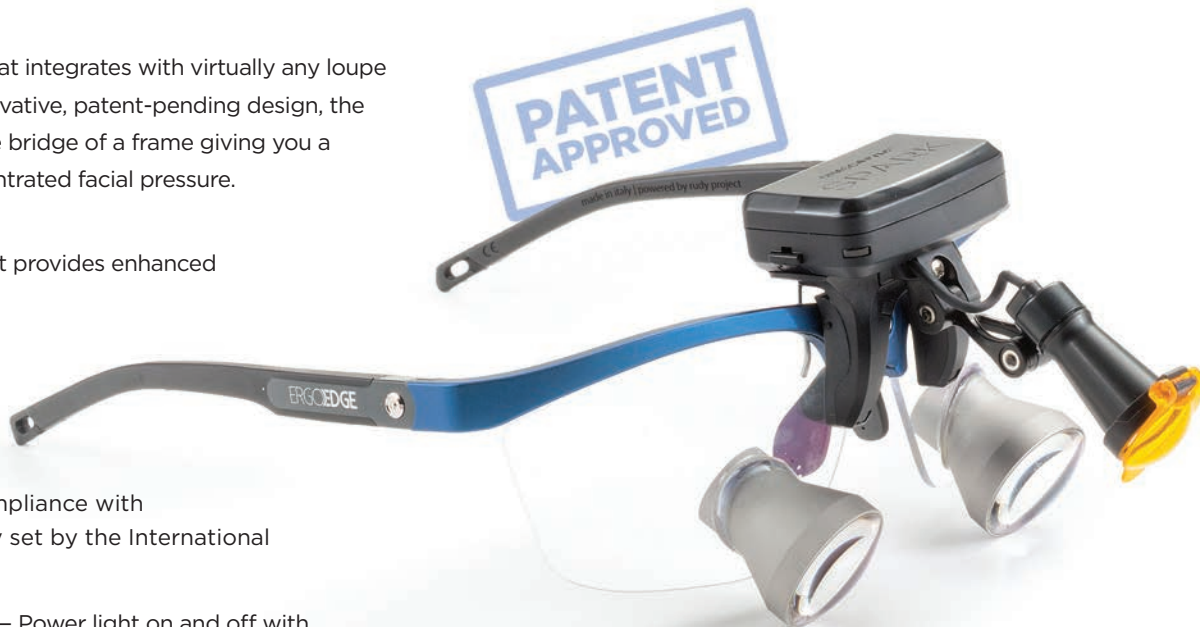
HEADLIGHTS

CORDLESS

SPARK™

The self-contained cordless headlight that integrates with virtually any loupe or eyewear frame style. Featuring an innovative, patent-pending design, the Spark dispenses weight evenly across the bridge of a frame giving you a more comfortable fit with minimal concentrated facial pressure.

- **Uniform Spot** — A precise focused light provides enhanced visibility during procedures.
- **Versatile Power Charger** — A micro USB charger offers added convenience for charging on the go.
- **Blue Light Compliant** — Maintains compliance with blue light testing standards for safety set by the International Electrotechnical Commission (IEC).
- **Advanced Capacitive Touch Controls** — Power light on and off with ease in between procedures and patient consultations.



SPECIFICATIONS Each Spark package includes power supply, charger, 2 rechargeable batteries, carrying case, 2 optical screwdrivers, cleaning cloth, curing filter.

Series	Battery Type	Weight	Light Intensity	Battery Life (2)	Charging Time
Spark	Lithium-ion	1.12 oz (31.8 g)	32 Lumens	6 hours	2 hours



HEADLIGHTS

ENDEAVOUR™

Our second generation of the Endeavour headlight, this portable system provides a precise focused beam of light that distributes light evenly across the field of view. Convenient capacitive touch controls allow you to quickly adjust light settings without reaching into your jacket pocket.

- **Uniform Spot** — The homogeneous round spot distributes light evenly across the field of view.
- **Constant-Current Technology** — Brightness will not diminish during the run-time of the battery pack.
- **Advanced Capacitive Touch Controls** — Quickly adjust light settings without having to reach into a coat or pants pocket.
- **Multiple Light Levels** — Delivers 3 light intensity levels up to 68 lumens.
- **Detachable Cable** — Lasting durability from Kevlar®-like fibers
- **Battery Enclosure** — Durability from extruded aluminum



SPECIFICATIONS

Series	Light Intensity	Intensity Control	Headlight Weight	Battery Type	Battery Weight	Battery Life	Charging Time
Endeavour	32/53/68 Lumens	Capacitive touch up to 68 Lumens	0.38 oz (10.8 g)	Lithium-ion	4.8 oz (138 g)	Up to 18 hours	Up to 3 hours



HEADLIGHTS

ENDEAVOUR™ XL

This patented headlight technology provides a precise beam of light that helps illuminate critical details that can often be overlooked by the naked eye. Utilizing constant-current technology, the headlight's light output will not diminish during the run-time of the battery pack.

- **Increased Light Output** — Produces 25% brighter light output than the Orasoptic™ Endeavour™ headlight.
- **Longer Run-Time** — Seize the day with up to 24 hours of battery life.
- **Advanced Capacitive Touch Controls** — Quickly adjust light settings without having to reach into a coat or pants pocket.
- **Multiple Light Levels** — Delivers a low, medium and high light intensity level up to 85 lumens.
- **Detachable Cable** — Lasting durability from Kevlar®-like fibers
- **Battery Enclosure** — Durability from extruded aluminum



25% brighter
than Endeavour

25% longer
battery run time
than Endeavour

24-hour
continuous
battery life



SPECIFICATIONS

Series	Light Intensity	Intensity Control	Headlight Weight	Battery Type	Battery Weight	Battery Life	Charging Time
Endeavour XL	53/68/85 Lumens	Capacitive touch up to 85 Lumens	0.38 oz (10.8 g)	Lithium-ion	7.3 oz (206 g)	Up to 24 hours	Up to 6 hours



FRAMES BUILT FOR LOUPES

Specializing in the design and manufacturing of surgical loupes, dental loupes, and hygiene loupes for over 35 years, we have made it our mission to provide superior visualization to clinicians across the globe.

Key features of our award-winning, innovative loupes are highlighted below.



BUILD THE PERFECT LOUPE

Building your dream loupe is as easy as a few clicks. Just let us know what loupe model you're interested in, and what frame style and color you want to mount it on, and you're on your way!

Our easy web interface will walk you right through every step in a matter of minutes.

orascopic.com/loupe-builder



LAB-TESTED RESOLUTION + BRIGHTNESS = CLARITY

The difference is striking. In a series of third-party lab tests, Orasoptic's 2.5x loupes consistently outperformed the competition with superior combined scores for field width, field depth, resolution and light transmission. Most notably, our scores were outstanding in the areas that contribute most to image clarity.

Third-party testing confirms that with best in class optical resolution and best in class light transmission, Orasoptic loupes deliver the clearest image quality in the industry.

► THE LIGHT TRANSMISSION TEST

This test measured how much light passes through the optic to the eye. The greater the light transmission, the brighter the image which together enhances image clarity.

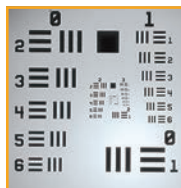
- For the light transmission test, Orasoptic's loupes measured:
- **40% better** than *Manufacturer A*
 - **14% better** than *Manufacturer B*
 - **20% better** than *Manufacturer C*

To learn more about the tests, visit [orasoptic.com](https://www.orasoptic.com).

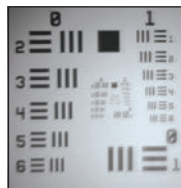
► **THE RESOLUTION TEST** Scores were determined by viewing the industry-standard USAF resolution target (below) through each telescope and performing the relevant calculations.

For the resolution test, Orasoptic's loupes measured:

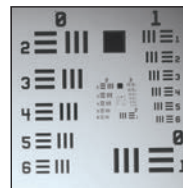
125% better than A | **12% better than B** | **26% better than C**



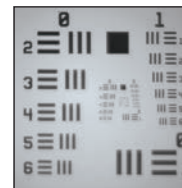
ORASOPTIC
(22.63 LP/mm)



Manufacturer A
(10.03 LP/mm)

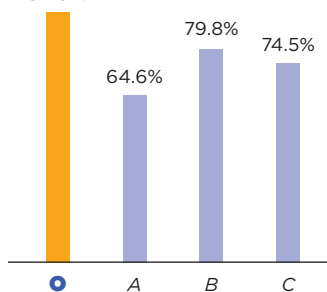


Manufacturer B
(20.16 LP/mm)



Manufacturer C
(17.96 LP/mm)

Percentage of Light
Passing Through the Optics
91.0%



Did You Know?

As our eyes age, less light reaches our retinas. Orasoptic loupes have a greater light transmission which allows you to maintain a high level of clarity and detail as you progress in your career.





Manufacturer A



ORASCOPTIC

NOTE: Simulated comparison of third-party lab tests conducted 2018





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Catre grupul de lucru
Pentru evaluarea COP nr.ocds-b3wdp1-MD-1582720266438
din 04.03.2020
din cadrul IMSP Institutul de Cardiologie

Declaratie

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Poata Vitalie_____

L.S.