

## Declaration of Conformity

### Product Family: Bioclear Plastic Instruments

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Bioclear Matrix Systems	3402 S Warner St, Ste A Tacoma, WA 98409 USA	

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

See below and attached pages for information on each variation.

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I Self Certified Rule <u>5</u>	Product is intended for transient use in a body orifice, specifically the oral cavity before the pharynx. Product is non-sterile, non-measuring and is not a re-usable surgical instrument.

The [Manufacturer] declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

**COMPANY REPRESENTATIVE:** Jennifer Wood

**TITLE:** Director of Legal and Regulatory

**PLACE:** Tacoma, WA, USA

**SIGNATURE:** 

**DATE:** 08/24/2021



PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Black Triangle Gauge	500111	<b>++D9495001118W</b>
Intended Purpose		Photo
<p>The Black Triangle Gauge is intended to be used to help determine which Black Triangle Matrix variation should be used for a dental procedure (usually closing open gingival embrasures). It does this by matching the color indicated on the gauge when inserted into a gingival embrasure from facial to lingual with colored tabs on the matrix. Contact with the patient is transient, meaning less than an hour, and the gauge should be removed after the appropriate matrix is determined. Black Triangle Gauges are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx. This is not a measuring device.</p>		

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Go/No-Go Probe	500121	<b>++D9495001218Z</b>
Intended Purpose		Photo
<p>The Go/No-Go Probe is intended to be used to help determine, by color coding for quick visualization, if a given cavity preparation can be fully cured in one layer or if two will be needed (for composites with a depth of cure of up to 5mm). Contact with the patient is transient, meaning less than an hour, and the gauge should be removed after the number of composite layers necessary are determined. Go/No-Go Probes are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx. This is not a measuring device.</p>		



PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Evolve Matrix Height Indicator	500122	<b>++D94950012293</b>
Intended Purpose	Photo	
<p>The Evolve Matrix Height Indicator is intended to be used to help determine, by color coding for quick visualization, if a given cavity preparation can be fully cured in one layer or if two will be needed (for composites with a depth of cure of up to 5mm). Additionally, it is intended to help determine which Bioclear Evolve Matrix variation should be used for a dental procedure by the number indicators printed on the Evolve Matrix Height Indicator which correspond with the numbers printed on the Evolve Matrices. Contact with the patient is transient, meaning less than an hour, and the gauge should be removed after the number of composite layers necessary and the correct matrix are determined. Evolve Matrix Height Indicators are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx. This is not a measuring device.</p>		

