

Product Safety Data Sheet

Page 1 of 4

1 - General Product View

Product trade name	ARTLINER® Premium Modules								
Route of Administration	Sharp needle modules (so called "safety cartridges") to be used with the electronic equipment dedicated for semi-permanent make-up procedures.								
Customs code	82079099 (exchangeable sharp needle accessories)								
Product characteristics	<div> <div> ArtLiner A-01-U - 1-ultra nano (1 x 0.16 mm) ArtLiner A-01-N1 - nano1 (1 x 0.18 mm) ArtLiner A-01-N2 - nano2 (1 x 0.20 mm) ArtLiner A-01-MIC - 1-micro (1 x 0.25 mm) ArtLiner A-01-R - 1-round (1 x 0.4 mm) ArtLiner A-03-MIC - 3-micro (3 x 0.18 mm) ArtLiner A-03-R - 3-round (3 x 0.25 mm) ArtLiner A-03-P - 3-power (3 x 0.3 mm) ArtLiner A-03-S - 3-sloped (3 x 0.3 mm) </div> <div> ArtLiner A-04-F - 4-flat (4 x 0.3 mm) ArtLiner A-05-P - 5-power (5 x 0.3 mm) ArtLiner A-05-S - 5-sloped (5 x 0.3 mm) ArtLiner A-05-M - 5-magnum (5 x 0.3 mm) ArtLiner A-05-R - 5-round (5 x 0.25 mm) ArtLiner A-07-R - 7-round (7 x 0.3 mm) ArtLiner A-07-P - 7-power (7 x 0.3 mm) ArtLiner A-07-M - 7-magnum (7 x 0.3 mm) </div> </div>								
Chemical composition	Name	C	Mn	Si	P	S	Ni	Cr	Mo
	%	0.12	2.0	1.0	0.045	0.03	8-10	17-19	-
Package system	Disposable blisters made with PE (transparent part) medical dialyzing paper (white part with print). Sterile. Packed per 10 units in a paper box.								
Shelf life period:	5 years from sterilisation date in original closed package								
Storage conditions	Store in a dry place with ambient temperature (5-35°C). Disposable sterile product. Use after opening.								

2 - Manufacturer

Marketing Authorization Holder (Name Address & Country)	BEAUTY INTERNATIONAL - pl. Wolnica 13/10, 31-060 Cracow, Poland, EU tel.: +48 12 345 28 49, info@artliner.eu , www.artliner.eu
Manufacturer of Finished Product (Name Address & Country)	BEAUTY INTERNATIONAL - pl. Wolnica 13/10, 31-060 Cracow, Poland, EU tel.: +48 12 345 28 49, info@artliner.eu , www.artliner.eu

3 - Hazards identification

Irritating for people with allergy on nickel.

4 - First – aid measures

Inhalation: not applicable Skin: allergy test required before all procedures due to nickel presence. If irritation occurs cleanse with saline. Obtain medical attention if needed. Eyeball scratch: obtain medical attention immediately. Ingestion: do not induce vomiting. Obtain medical attention immediately.

5 - Fire – fighting measures

Suitable extinguishing media: not applicable Unsuitable extinguishing media: not applicable Additional information: not applicable Special hazards: none (not inflammable and not explosive product)

6 - Accidental Release Measures

Personal precautions Do not eat or drink when working, wash hands before breaks and after work. Avoid contact with eyeballs. Do not swallow.
Environmental precautions: not applicable / not required

Product Safety Data Sheet

Page 2 of 4

7 - Handling and Storage

Information for safe handling

Use normal standards of industrial hygiene for handling chemicals. Avoid contact with eyeballs. Do not swallow. Disposable. Store in a dry place with ambient temperature (5-35°C). Keep container tightly closed when it is not in use. Keep away from humidity and fire sources.

Information about protection against explosions and fires: without (not inflammable and not explosive product)

Further information about storage conditions: without

8 - Exposure Controls and Personal Protection

Components with critical values that require monitoring at the workplace (exposure limits): without

Personal protective equipment: not applicable / not required. Use typical security standards for sharp tools.

General protective and hygiene measures: use typical standards of industrial hygiene.

Disposing: must be disposed in accordance with local by laws regarding used sharps disposal.

Respiratory protection: not applicable / not required

Hand protection: use typical security standards for sharp tools.

Eye Protection: use typical security standards for sharp tools.

Body Protection: use typical security standards for sharp tools.

9 - Physical and chemical properties

Form/texture: stainless steel needles in different configurations inside of plastic module with a spring made with stainless steel

Colour: silver needles connected into a tube located with silver springs in a semi-transparent grey plastic enclosure (safety cartridge)

Odour: not applicable

PH Value: not applicable

Relevant safety date: 5 years since sterilisation date

Boiling point / rang: not applicable / not required

Vapor pressure: not applicable / not required

Density: not applicable / not required

Solvent – separation test: not applicable / not required

Solubility in water: not applicable / not required

Flow time: not applicable / not required

Viscosity: not applicable / not required

10 - Stability and reactivity

Conditions to avoid: keep away from humidity and fire sources.

Materials to avoid: not applicable

11 - Toxicological information

Not recommended for people with allergy on nickel.

12 - Ecological information

Details on elimination (persistence / degradability)

Disposing: must be disposed in accordance with local by laws regarding used sharps disposal.

Methods for cleaning up: without – disposable product.

Additional ecological information: without - no data is currently available.

Additional ecological data: without - no data is currently available.

Specification: without - no data is currently available.

Value / dosage: without - no data is currently available.

Product Safety Data Sheet

Page 3 of 4

13 - Disposal considerations

Must be disposed in accordance with national/local legislative requirements for used sharps disposal.
Container disposal as for waste product disposal.

14 - Side effects

No adverse health effects have been observed or have been come to our knowledge if proper use is provided.
Not recommended for people with allergy on nickel.

15 - Regulatory information

Classification of the product

CE marked, sterile and disposable sharp needle (modules/safety cartridges) for beauty procedures.

Danger symbol and danger designation

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Hazard – determining components of labelling

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Risk – Phrases

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Safety – Phrases

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.
Product contain security membrane and sealed enclosure that prevent fluid from flowing backwards into the device.

National regulatory information

Sterilized by EO. The products comply with ISO 11737 standard (Sterilization of medical devices - Microbiological methods – Part 2).
CE marked.

Regulation on inflammable liquids: not applicable / no data is currently available.

Emission control act: not applicable / no data is currently available.

Water pollution classification: not applicable / No data is currently available.

16 - Other information

Further information: all information targeted to the customers are located on the label of the product. There are no additional flyers inside the product.

R-phrases of components: without

This is to certify that the information contained herein is true and correct.

Name and title of responsible official in the company: **SYLWIA MICHNO – CEO/Founder.**

Notice: Information contained in this data sheet is based on current knowledge and usage, customers should satisfy themselves as to the suitability of this product for their own particular use.
This information is offered in good faith. Each user of this product needs to evaluate individual conditions of use (including the appropriate beauty procedures) to prevent from damages of patient's skin and/or negative side effects.

All detailed instructions that refer to the manual of permanent makeup procedures (pre- and after-care) are obtained during professional training locally by Authorised Trainer of ArtLiner®.
Beauty International, the legal owner of ArtLiner® brand assumed no responsibility for injury to the recipient or third parties, or for any health damage to any person resulting from misuse of the product without professional training confirmed by Competency Certificate issued by the Authorized Master Trainer of ArtLiner®.

ArtLiner® is a registered Trade Mark of Beauty International company.

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Product Safety Data Sheet

Page 4 of 4